Chapter 5

ET Liver Allocation System (ELAS)

Change record

Date	Author	Version	Change reference
05-03-25	A.J.T. Jens	6.13	Textual adjustment – 5.2.5.2 Addition NSE oncological indication NL - 5.9.1.6 NL Center offers for DCD >= 61 y.o - 5.3.10.1.5
17-12-24	M van Bruchem	6.12	Addendum C – reMELD-Na updated: mandatory serum sodium entry for all non-German recipients
05-11-24	M de Rosner – van Rosmalen	6.11	Addendum C – reMELD-Na added
28-08-24	M de Rosner – van Rosmalen	6.10	Dutch study NSE 1 auditor system
23-04-24	M van Bruchem	6.9	Transmet study deleted as no longer active
27-03-24	M de Rosner – van Rosmalen	6.8	Textual clarification of obligation process
17-01-23	M van Bruchem	6.7	NSE score for national studies directly granted via MELD application, corrected in 5.9.1.6. Transmet study temporarily closed.
18-10-23	M de Rosner – van Rosmalen	6.6	Correction of table 5.9.1.6
12-09-23	M de Rosner – van Rosmalen	6.5	R-LAC05.16 HU Li impending int failure on Li WL R-LAC06.16 HU Li in need of intestine R-LAC07.16 ACO status request including pancreas for anatomical reasons R-LAC01.23 Medication with influence on the INR, Change SE PSC Germany Automated reconfirmation SE with audit the Netherlands
07-08-23	M de Rosner – van Rosmalen	6.4	Addition of exceptional points for CRM the Netherlands
18-10-22	M de Rosner – van Rosmalen	6.3	Implementation of new criteria SE HCC the Netherlands
10-03-22	M de Rosner – van Rosmalen	6.2	Implementation R_LAC 07.20 SE HCC criteria for Austria
03-01-22	M de Rosner – van Rosmalen	6.1	Correction in numbering of the SE HCC criteria 3 and 4

Date	Author	Version	Change reference
02-11-21	M de Rosner – van Rosmalen	6.0	R-LAC07.20 – Adapt accepted ways of diagnosis of Hepatocellular Carcinoma (for all countries besides Germany and Austria) P-LAC02.20 – HU donor profile R-LAC01.20 – Rephrasal of R-LAC03.18 - HU liver criteria -Acute liver failure R-LAC09.19 – Definition of pediatric liver patient R-LAC09.18 – HU liver criteria - SE hepatic artery thrombosis (Germany) R-LAC08.18 – HU liver criteria –Hepatic artery thrombosis R-LAC07.18 – HU liver criteria – Primary graft non-function R-LAC06.18 – HU liver criteria – Anhepatic state R-LAC05.18 – HU liver criteria – Budd-Chiari syndome R-LAC04.18 – HU liver criteria – Wilson disease R-LAC02.18 – HU liver criteria – General criteria Automation of NSE reconfirmation the Netherlands
16-03-21	M de Rosner – van Rosmalen	5.30	Adaptation diagnoses for SE HCC, NSE criteria guidelines added, TOM study stopped per 28-02-21
10-02-21	M de Rosner – van Rosmalen	5.29	Textual adaptation of domino donor diagnoses.
08-12-20	M de Rosner – van Rosmalen	5.19	Clarification of 365 days for Dutch SE Polycystic liver disease.
09-11-20	M de Rosner – van Rosmalen	5.18	Clarification of re-confirmation period of labMELD based SEs
05-11-19	M de Rosner – van Rosmalen	5.17	NSE HCC criteria for Germany according to TOM-study added to the SE application
24-09-19	M de Rosner – van Rosmalen	5.16	Change in SE urea cycle disorder (all countries), SE HAT and SE hyperoxaluria (non-German countries)
23-09-19	M de Rosner – van Rosmalen	5.15	Check for correctness, completeness and approval of the entire manual by the ELIAC incl version of Sept 24
18-06-19	M de Rosner – van Rosmalen	5.14	Addition SE HCC Belgium according to up-to-seven
18-06-19	M de Rosner – van Rosmalen	5.13	Manual review for content, clarity and accuracy: Manual page 11-31 approved in ELIAC 21-06-18 Manual page 31-60 approved in ELIAC 10-05-19
18-06-19	M de Rosner – van Rosmalen	5.12	Change of the terms HB and NHB to DBD and DCD
20-02-2019	J. de Boer	5.11	Adaptation HU criteria for Hepatoblastoma in Germany (5.2.1.1)
29-01-2019	M de Rosner – van Rosmalen	5.10	Extracorporeal liver support as replacement of term MARS therapy
02-11-2018	M de Rosner – van Rosmalen	5.9	Clarification of Belgian DCD center offer sequence
13-02-2018	M de Rosner – van Rosmalen	5.8	Textual adjustments about email notifications
24-11-2017	M de Rosner – van Rosmalen	5.7	Removing text with regard to email notifications
14-09-2017	M de Rosner – van Rosmalen	5.6	Clarifying the ENIS diagnoses required per SE, clarification procedure for obligations in DCD liver allocation

Date	Author	Version	Change reference
09-08-2017	M de Rosner – van Rosmalen	5.6	Clarification back up procedure for intended liver split
20-06-2017	M de Rosner – van Rosmalen	5.5	Implementation of SE NET Germany
17-05-2017	M de Rosner – van Rosmalen	5.4	Adaptation procedure for SE downstaged HCC (3c) for Belgium
16-05-2017	M de Rosner – van Rosmalen	5.3	Implementation R-LAC02.14 Germany, R-LAC03.14 and R-LAC04.14 all countries. Adaptation INR values on the HU request form
22-11-2016	M de Rosner – van Rosmalen	5.2	Implementation of P-LAC10.16
27-10-2016	M de Rosner – van Rosmalen	5.1	Implementation R-LAC04.13 MARS Therapy
17-05-2016	M de Rosner – van Rosmalen	5.0	Implementation R-LAC02.13, R-LAC03.13 for Germany, adaptation SE HCC Germany, Implementation of SE hepatoblastoma and SE urea cycle disorder Hungary, Implementation of NSE system Croatia
			Older changes can be provided upon request

The Eurotransplant Manual contains the rules and regulations for the implementation and specification of national legislation and national guidelines for waiting list management, organ procurement and allocation. It has been prepared with the best of knowledge and the utmost care. In case of discrepancies between the content of this manual and national binding provisions, the following applies:

- In so far, as provisions about the acceptance of organ patients to the waiting list are concerned, this manual has only an informative character. Only the national provisions which are applicable for the transplant centers are relevant and legally binding.
- For the allocation of organs only the national provisions are legally binding. The display of the allocation provisions in this Manual are based on these legally binding national provisions. As far as necessary, they have been specified by Eurotransplant in this Manual. Deviations from such specifying Eurotransplant provisions cannot be considered as a breach of the national provisions as long as the latter are not violated. Eurotransplant cannot be held liable for a potentially wrongful description in this Manual of procedures, in connection with the organ allocation, as long as the actual allocation follows national provisions.

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5.1 MELD score

The Model for End-stage Liver Disease (MELD) scoring system was developed by the Organ Procurement and Transplantation network (OPTN)/United Network for Organ Sharing (UNOS) and implemented in February 2002. The ET Board decided in 2003 to implement MELD for liver allocation in Eurotransplant[1].

The calculation of an individual's MELD score is based on three objective lab parameters, i.e. International Normalized Ratio (INR), creatinine, and bilirubin.

MELD aims at stratifying patients by their disease severity according to a score estimating the 3-month probability of death on the waiting list.

A high MELD indicates severe illness, thus a patient in urgent need of transplantation. Patients are stratified in a descending order, starting with the highest MELD.

MELD is only applied for the listing and matching of elective (T) patients with an end-stage chronic liver disease, i.e. patients not eligible for status High Urgency (HU) or Approved Combined Organ (ACO).

Patients can, at the initiative of the transplant center, have an exceptional MELD assigned if disease severity is not accurately reflected by lab MELD.

Transplant centers are responsible for the waiting list management. A patient's current status in ENIS must reflect the current clinical status. Any change in a patient's status must be entered immediately.

5.1.1 MELD formula

The MELD formula is calculated as follows:

MELD Score = 0.957 x Log_e (creatinine mg/dL) + 0. 378 x Log_e (bilirubin mg/dL) + 1.120 x Log_e (INR) + 0.643

5.1.1.1 Explanation to MELD formula

The MELD formula is handled as follows:

- MELD score is multiplied by 10 and rounded to the nearest whole number;
- Laboratory values less than 1.0 are set to 1.0 in MELD score calculation;
- Maximum S-Creatinine in the MELD score equation is 4.0 mg/dl. The MELD formula calculates '0.957 x Loge(4.0)' in S-Creatinine values >4.0 mg/dl;
- A positive answer to 'Had Dialysis twice within a week prior to Serum Creatinine test?'[2] will result in a S-Creatinine of 4.0 mg/dl applied in the MELD formula;
- The maximum *lab MELD* applied in the matching is 40, i.e. lab MELD scores exceeding 40 are adjusted to 40.
- The use of any vitamin K antagonists or direct oral anticoagulants (DOAC) influences the INR value in the MELD score equation (see Chapter *Registration of elective (T) patients*).

[1] RLAC01.03, confirmed by ET Board in May 2003; UNOS policy at www.unos.org.
[2] The answer can only be Yes if "dialysis" is equal to renal replacement therapy.

5.1.1.2 MELD definitions

In matching procedures it will be necessary to make a distinction between a calculated MELD score and those that are not based on the three lab values, i.e. exceptions. In this regard, the following expressions are introduced:

MELD	Descriptions
lab MELD	MELD scores calculated after data entry of lab values or downgraded lab MELD scores if unrecertified.
pediatric MELD	PELD alternative for children <18 years of age.
exceptional MELD	MELD scores granted for either standard (SE) or non-standard exceptions (NSE).
match MELD	The MELD score applied in the match, i.e. either lab MELD, pediatric MELD or exceptional MELD. In all cases in the benefit of the patient, i.e. the highest valid MELD at time of matching.

5.1.1.2.1 **Lab MELD**

The lab MELD is the (downgraded) calculated MELD score of a patient. Calculation is performed upon (re)registration, scheduled or voluntary recertification.
Downgrades are performed if recertification is not performed on time.

The lab MELD is applied in the matching:
in all T patients;
if an ET donor liver is offered to patients from non-national ET donor countries (except obligation-to-offer organs);
if non-ET donors are offered to and allocated within ET.

The maximum lab MELD applied in the matching is 40, i.e. lab MELD scores >40 are capped at 40 in the matching.

5.1.1.2.2 **Additional Lab values**

At time of listing and with every MELD update the following four additional lab values can be reported to Eurotransplant:

-Serum Sodium
-Serum Cholinesterase
-Serum Ferritin
-Alpha feto protein (AFP)[3]

These lab values might be helpful in further improving liver allocation via a modified MELD-score, therefore they should be reported to Eurotransplant.

For pediatric patients, the Serum Albumin is requested at time of listing and with every MELD update. This value is not taken into account in the labMELD score.

[3] as of December 12, 2015

5.1.1.2.3 **Exceptional MELD**

An exceptional MELD is applied in eligible standard exception (SE) or non-standard exception (NSE) patients. The exceptional MELD is not based on the lab values, but has a fixed initial value and can be upgraded at 90-day intervals.

Patients have the exceptional MELD applied in matching procedures if the exceptional MELD is higher than the current lab MELD.

Patients have their lab MELD applied in matching procedures if the lab MELD is higher than the current exceptional MELD.

5.1.1.2.4 **Pediatric MELD**

All pediatric patients registered under the age of 18 years are automatically assigned the initial pediatric MELD (16 years of age for Germany). Upgrades are automatically performed after 90 days if the patient has not been transplanted. Upgrades are performed until the patient reaches the age threshold of 18 years (16 years for Germany). If the patient turns 18 years (16 years for Germany) and is still awaiting liver transplantation then the (upgraded) pediatric MELD is frozen and the patient continues to have that frozen pediatric MELD applied in the match until transplantation.

5.1.1.3 Recertification

Patients registered on the waiting list must be recertified at set intervals. The length of the interval until the following recertification depends on country- and urgency-specific rules.

Transplant centers are responsible for the correctness of the data entered to recertify the patients' lab MELD.

See chapter *5.5.1 Quality assurance and data verification* for the required data in case of a standard or random audit.

5.1.1.3.1 **Voluntary updates**

A transplant center can update a patient's lab MELD voluntarily at any time during the regular recertification interval. A higher lab MELD would improve this patient's chance for a timely transplantation. A lower lab MELD would prevent jeopardizing other patient's chance for a timely transplantation.

A patient's voluntarily updated lab MELD is immediately applied in the matching.

5.1.1.3.2 **Scheduled recertification**

A lab MELD is expected to be recertified by the transplant centers at scheduled intervals.

Data must not be older than the specified expiry date at data entry. Also most recent data must be used. If lab values are older than the expiry date, data will not be accepted; urgency and country-specific rules apply.

Note: Information on the lab sheet (patient identification and lab values) is not allowed to be handwritten (except for the ET number of the patient).

5.1.1.3.2.1 ET recertification schedule

MELD	lab MELD expires after	Notification before expiry	Expiry date of lab values at data entry
MELD ≥25	7 d	2 d	not older than 48 h
MELD ≤24, >18	30 d	7 d	not older than 7 d
MELD ≤18, ≥11	90 d	14 d	not older than 14 d
MELD ≤10	365 d	30 d	not older than 30 d

5.1.1.3.2.2 Center work list

Transplant centers will have access to specific reports provided through the MELD web application accessible through the ET member site at www.eurotransplant.org.

5.1.1.4 Exceptions

Patients whose disease severity is not adequately reflected by lab MELD can, at the initiative of the transplant center, be requested for an exceptional MELD.

5.1.1.4.1 **Standard exception (SE)**

Patients can be requested for a standard exception (SE) at any time after registration; disease and country-specific rules apply. The list of SE defines:
diseases eligible for SE;
disease-specific SE criteria;
initial MELD equivalent assigned at time of approval;
time interval until upgrade/recertification
urgency/MELD equivalent assigned upon qualifying for upgrade.

Patients must fulfill country and disease-specific criteria before the exceptional MELD can be approved.

If the exceptional MELD was approved, then this status is granted for the duration of 90 days. Before the expiry of this 90-day period the SE status must be reconfirmed by accessing the web application again; disease and country-specific rules apply.

5.1.1.4.2 **Non-standard exception (NSE)**

Patients who are not eligible for an SE can be requested for a non-standard exception (NSE) at any time after registration; disease and country-specific rules apply.

NSE patients have to be prospectively audited by a national audit group; national audit rules apply. Patients must be approved by the national audit group before the exceptional MELD can be approved.

If the non-standard exception was approved, then this status is granted for the duration of 90 days. Before the expiry of this 90-day period the NSE status must be reconfirmed.

Patients who have been approved for NSE by the national audit group are assigned an initial exceptional MELD of 10% equivalent of 3-month probability of death; country-specific rules apply.

5.1.1.5 Reconfirmation of exceptional MELD

Patients with an exceptional MELD have to be reconfirmed before the end of the 90-day period. Centers can find information in the MELD-application; exception and country-specific rules apply.

Voluntary reconfirmations before the notified period are not possible.

5.2 Urgencies

Urgency codes are used to classify patients on the waiting list and to prioritize patients in the match and allocation procedure. Urgency codes reflect medical urgency and transplantability.

Medical Urgency		Priority	Obligation to offer
HU	High Urgency	Internationally 1st	Yes
ACO	Approved Combined Organ	Internationally 2nd	Yes
T	Elective patients	MELD scores in descending order	No
NT	Temporarily not-transplantable	not matched	-

5.2.1 High Urgency (HU)

The High Urgency (HU) liver status provides international priority above ACO and elective patients. The HU status can be requested for cases of acute liver failure, graft failure after transplantation and in specified other cases. The HU liver status is valid for 14 days.

The standard criteria for the HU liver diagnoses have been rephrased and/or clarified by the ELIAC in HU liver consensus meetings[4]. The detailed description of the recommendations and background can be found separately on the Eurotransplant member site.

General criteria for the HU liver status[5]:

• The HU status should be granted for eligible liver transplantation patients with an "imminent" risk of death

• Patients with acute on chronic liver disease (AoCLF) (besides the two pediatric indications and exceptions for Wilson disease and Budd-Chiari syndrome) are not eligible for HU listing.

• Patients with secondary liver failure have to undergo an individual audit.

General remarks[6]:

- *Encephalopathy is an absolute prerequisite for the HU status, in combination with the criteria below. Patients with acute liver failure without encephalopathy need to undergo an individual HU audit.*
- *HU status should be granted for patients with acute liver failure fulfilling Kings College criteria for paracetamol intoxication or non-paracetamol intoxication, or fulfilling Clichy criteria in case of hepatitis B only.*
- *Pediatric hepatic encephalopathy is classified according to the PALF study group criteria*

A transplant center should place the patient in a status other than HU, if the clinical status of a patient improves, or remove the patient from the waiting list if he deteriorates beyond transplantability.

[4] HU liver consensus meetings Sept 06, 2017, ELIAC meeting Nov 30, 2017, March 19, 2018, June 21, 2018, Nov 21, 2018, May 10, 2019. The new criteria are implemented on November 2, 2021

[5] R-LAC02.18 - HU liver criteria - General criteria

[6] R-LAC01.20 - Rephrasal of P-LAC02.19 and R-LAC03.18 - HU liver criteria -Acute liver failure

5.2.1.1 Diagnoses for HU liver status

HU diagnoses:
- Acute liver failure (ALF) defined by King's College;
- Acute liver failure due to HBV defined by Clichy criteria
- Acute liver failure due to rapidly progressive Budd-Chiari Syndrome;
- Acute liver failure due to rapidly progressive Morbus Wilson[7];
- Anhepatic state.
- PALF Study Group criteria on Pediatric Hepatic Encephalopathy;
- Hepatoblastoma[8];
- Urea cycle disorder/ organic acidemia[9];
- Urgent liver transplant for impending intestinal failure[10]
- Urgent combined liver and intestine transplantation[11]
- Acute graft failure after transplantation due to primary graft non-function or hepatic artery thrombosis.

5.2.1.2 ALF, King's College criteria[12]

5.2.1.2.1 ALF, Acetaminophen (Paracetamol) intoxication

King's college criteria for acute liver failure due to paracetamol intoxication *(in absence of cirrhosis)*

Hepatic encephalopathy ≥grade 1 present,

And *fulfills at least one of the two following criteria:*
1. *Arterial pH <7.25 despite fluid resuscitation and >24 h since ingestion* **and / or***
2. *S-lactate >3.5 mmol/L on admission or >3.0 mmol/L after[13] fluid resuscitation*

Or *fulfills all 3 criteria below:*
1. *Hepatic encephalopathy ≥grade 3 **and***
2. *Anuria/s-creatinine >300 µmol/L (3.4 mg/dl) **and***
3. *INR >6.5*

** Any pH-value in measurements >24 h since ingestion of paracetamol*

5.2.1.2.2 ALF, non-paracetamol intoxication

King's college criteria for acute liver failure not due to paracetamol *(absence of cirrhosis)*

Fulfills:
1. *INR >6.5 (PT>100 sec) **and***
2. *Hepatic encephalopathy ≥grade 1*

Or *Hepatic encephalopathy ≥grade 1 **and** fulfills 3 out 5 criteria:*
1. *Hepatitis of unknown aetiology, idiosyncratic drug reaction, toxin induced **and/or***
2. *Age <10 years or >40 years **and/or***

[7] Decided on ELIAC meeting September 24,2012
[8] Implemented as direct HU indication (SE no longer applicable) as of May 16,2017
[9] Implemented and adapted as direct HU indication (SE no longer applicable) as of September 24, 2019
[10] R-LAC05.16 Intestine – HU Li impending int failure on Li WL, implemented as of September 12, 2023
[11] R-LAC06.16 Intestine – HU Li in need of intestine, implemented as of September 12, 2023
[12] O'Grady JG, Schalm SW, Williams R. Early indicators of prognosis in fulminant hepatic failure. Gastroenterology 1989; 97: 439-445 and R-LAC01.20 - Rephrasal of R-LAC03.18 - HU liver criteria -Acute liver failure
[13] For Germany: 4 hours after fluid resuscitation. See German RL

3. *Interval jaundice and onset of hepatic encephalopathy >7 days* ***and/or***
4. *Total bilirubin >300 µmol/L (>17.5 mg/dl)* ***and/or***
5. *INR >3.5*

5.2.1.3 ALF, Clichy criteria[14]

Clichy criteria for hepatitis B virus-induced acute liver failure *(absence of cirrhosis)*

Fulfills:

1. *Hepatic encephalopathy ≥grade 3* ***and***
2. *Factor V<20%[15] of normal if age <30 year* ***or***
   Factor V <30% if age ≥30 year

5.2.1.4 Acute liver failure due to rapidly progressive Budd-Chiari Syndrome (BCS)

- *Only patients with an acute presentation of BCS evolving into acute liver failure are eligible for HU listing. Cirrhosis may be present.*
- *Patients should be worked up for inherited or acquired coagulopathy.*
- *In patients with myeloproliferative disease, an oncological consult is required to specify the prognosis, in particular under the condition of chronic immunosuppression.*
- *For a HU application, it is necessary to document that TIPS/revascularization was unsuccessful or that due to anatomical/technical circumstances a successful procedure cannot be performed.*

Criteria:

Fulfills:
Rotterdam score > 1.5*

**Rotterdam score*	
$1.27 \times \text{hepatic encephalopathy}_a + 1.04 \times \text{ascites}_b + 0.72 \times \text{INR}_c + 0.004 \times \text{total bilirubin}_d$	
$_a$ *hepatic encephalopathy*	*present = 1, absent = 0;*
$_b$ *ascites*	*present = 1, absent = 0;*
$_c$ *INR*	*≥2,3 = 1, <2.3 = 0;*
$_d$ *total bilirubin*	*in µmol/L*

5.2.1.5 Acute liver failure due to rapidly progressive Morbus Wilson[16]

- *Only patients with an acute presentation of Wilson disease evolving into acute liver failure are eligible for HU listing. Cirrhosis may be present.*
- *Cases of acute on known chronic Wilson disease should undergo individual audit.*

Criteria:

Fulfills ***both*** *criteria:*

1. *INR >1.5* ***and***
2. *hepatic encephalopathy ≥grade 1*

and

Fulfills ***2*** *out of 8 criteria:*

[14] Berneau J, Goudeau A, Poynard T et al. Multivariate analysis of prognostic factors in fulminant hepatitis B. Hepatology 1986; 6: 648-651 and R-LAC01.20 - Rephrasal of R-LAC03.18 - HU liver criteria -Acute liver failure
[15] For Germany: FV ≤20% <30 year and ≤30% ≥30 year. See German RL
[16] R-LAC04.18 - HU liver criteria - Wilson disease

1. *Kayser-Fleisher rings** ***and/or***
2. *Coombs-negative hemolytic anemia* ***and/or***
3. *hepatic copper concentration >4 µmol/g* ***and/or***
4. *urinary copper >9 µmol/24 h* ***and/or***
5. *serum ceruloplasmin <0.15 g/L* ***and/or***
6. *below normal or normal alkaline phosphatase (AP) and/or AST below 300IU/L* ***and/or***
7. *presence of ATP7B gene mutations* ***and/or***
8. *copper deposition on brain MRI** or typical neurology****

* Report by ophthalmologist required
** MRI report required
*** Neurology consult required

5.2.1.6 Anhepatic state secondary to ALF[17]

Criteria:

Total hepatectomy to control traumatic liver hemorrhage ***or***
Total hepatectomy for "toxic liver syndrome" in the setting of fulminant hepatic failure.

5.2.1.7 PALF Study Group criteria on Pediatric Hepatic Encephalopathy[18]

For pediatric patients specific criteria with regard to encephalopathy according to the PALF Study Group criteria on Pediatric Hepatic Encephalopathy are installed.

Criteria:

Fulfills ***both*** *criteria:*
1. *Biochemical proof of acute liver failure (above normal values of ASAT and ALAT)* ***and****,*
2. *INR ≥ 2.0, not correctable with parenteral Vitamin K*

(presence of hepatic encephalopathy is not mandatory)

Or

Fulfills ***all 3*** *criteria:*
1. *Biochemical proof of acute liver failure (above normal values of ASAT and ALAT)* ***and***
2. *INR ≥ 1.5 <2.0 not correctable with parenteral Vitamin K* ***and***
3. *Hepatic encephalopathy (< 3 years of age according to Whitington ≥ 3 years of age according to adult criteria)*

5.2.1.8 Hepatoblastoma

The diagnosis hepatoblastoma has changed to a direct HU indication (SE is no longer applicable)[19]

Criteria:
- Patient is <16 years old **and**
- Hepatoblastoma proven in liver biopsy and
- Patient is suitable for transplantation after chemotherapeutical treatment **and**
- Absence or complete resection of vital extrahepatic metastases **and**
- Germany: not curable by partial liver resection

[17] R-LAC06.18 - HU liver criteria - Anhepatic state
[18] R-LAC01.20 - Rephrasal of R-LAC03.18 - HU liver criteria -Acute liver failure
[19] Implemented as direct HU indication (SE no longer applicable) as of May 16,2017

5.2.1.9 Urea cycle disorder/organic acidemia

The diagnosis urea cycle disorder/organic acidemia has changed to a direct HU indication (SE is no longer applicable)[20].

Criteria:
Patients are eligible for High Urgency status for urea cycle disorder/organic acidemia if:
- Patient is <3 years old ***and***
- Has a urea cycle disorder or organic acidemia ***and***
- Patient is a suitable patient for liver transplantation

5.2.1.10 Urgent liver transplant for impending intestinal failure[21]

In case a timely liver transplantation is expected to avoid the necessity of an intestine transplantation, HU liver status can be granted after audit by the ELIAC in which the advice of the intestine auditor group will be obtained.

Registration on the intestine waiting list is not mandatory.

5.2.1.11 Urgent combined liver and intestine transplantation[22]

HU liver status can be granted to recipients in need of transplantation of combined intestine and liver grafts or multivisceral grafts (including liver and intestine) in case of documented diffuse necrosis of one or more of these organs (due to vascular thrombosis) after audit by the ELIAC (of which one intestine auditor).

5.2.1.12 Acute graft failure after transplantation

5.2.1.12.1 *Primary graft Non-Function (PNF)[23]*

HU status for PNF should be granted up to 14 days post-transplant.

Criteria*:*
PNF within 14 days after LT ***and***
Peak AST ≥3000IU/L ***and***

1 out of 3 criteria:

1. *INR ≥2.5* ***and/or***
2. *s-lactate ≥4 mmol/L* ***and/or***
3. *total bilirubin ≥10 mg/dL*

(values measured on postoperative day 3, biliary obstruction being excluded)

The previous transplant must be registered in ENIS.

[20] Implemented as direct HU indication (SE no longer applicable) as of 24-09-19
[21] R-LAC05.16 Intestine – HU Li impending int failure on Li WL, implemented as of September 12, 2023
[22] R-LAC06.16 Intestine – HU Li in need of intestine, implemented as of September 12, 2023
[23] R-LAC07.18 - HU liver criteria - Primary graft non-function

5.2.1.12.2 *Hepatic Artery Thrombosis (HAT)*[24]

A HU liver request for HAT can be requested up to 90 days after transplantation. Patients with HAT without graft failure can apply for a SE

HU liver status for re-transplantation due to hepatic artery thrombosis (HAT) can be granted in case of:

-Graft failure associated with HAT ***and***

-Occurrence ≤90 days after liver transplantation ***and***

-Peak AST ≥3000IU/L ***and***

-1 out of 3 criteria:

1. *INR ≥2.5* ***and/or***
2. *Arterial pH ≤ 7.3 or venous pH ≤ 7.25* ***and/or***
3. *s-lactate ≥4 mmol/L*

The previous transplant must be registered in ENIS.

5.2.1.12.3 *Portal Vein Thrombosis*

No standard criteria specified. Request will be audited.

5.2.1.12.4 *ITBL*

No standard criteria specified. Request will be audited.

5.2.1.13 HU audit

The corresponding HU form, either first or retransplant (see Forms at www.eurotransplant.org), must be completed on all items and sent to the ET duty desk. The following criteria have to be met:

- Key element of the request is a detailed and signed motivation letter in the English language
- Copies of all findings (lab values, X-ray, CT, MRI, pathology reports, biopsy, ultrasound etc.) mentioned in the motivation letter have to be included.
- Lab values should not be older than 12 hours and not written by hand.

The ET Medical Staff evaluates the request according to the HU criteria. The HU status is granted if the criteria are met. Upon approval the urgency is changed in ENIS.

In case the criteria are not fulfilled or in case of doubtful clinical situation, two members of the ELIAC, are contacted to evaluate the HU request. The selected auditors are ELIAC members not active in the country of the requesting center. In case of split decision, a third ELIAC member will decide on the approval or denial of the HU request.

In case of HU requests for pediatric patients, preferably all auditors evaluating the HU request should have a pediatric background (appointed by the national competent

[24] R-LAC 08.18 HU liver criteria – Hepatic artery thrombosis

authorities)[25].

To ensure independent decision-making by the auditors, auditor names should not be disclosed to the requesting center and other auditors involved.
No auditor names should be made known to national competent authorities[26].

A remote center cannot assign urgency HU in ENIS.

In case a center has entered in ENIS that they have no capacity for transplantation, HU patients will still receive the offer.

5.2.1.14 HU Re-evaluation[27]

The HU status for liver transplant patients has to be re-evaluated every 14 days.
At the time of re-evaluation, the number and details of a turned down liver organ offer in the preceding 14 days have to be reported to the auditors.

In case no re-evaluation is sent in, the HU status will be stopped the next day at 8.00 (am) hrs.

5.2.1.15 HU patient not transplantable[28]

Patients in HU status who become (temporarily) not transplantable have to be reported as NT and will at that moment lose the HU status including the so far accumulated HU days. If these patients regain the T (Transplantable) status, a new HU request has to be sent to Eurotransplant.

5.2.1.16 Appeal to Audit decision [29]

If the center does not agree the judgment of the auditors an appeal can be sent to Eurotransplant. The appeal will be sent to the Auditors that already evaluated the original request. In case one or several auditors are not available and new auditors have to be approached, the previous decisions will be added to the request.
In case of a second or higher appeal, the request will be evaluated during daytime.

5.2.2 Approved Combined Organ (ACO)[30]

Patients in need of a multi-organ liver transplant -except liver+kidney- can be requested for status ACO. A patient with ACO status is prioritized above Transplantable patients on the liver match, below the patients with HU status. In case of a pediatric donor, pediatric patients with the ACO status are prioritized over adult patients with an ACO status.

An ACO status can be requested for cases with the need for pancreas for anatomical reasons and for endocrine reasons.

In case of an ACO request for multivisceral transplantations or modified multivisceral transplantations (including intestine and pancreas), where the pancreas is requested for anatomical reasons, a request with justification regarding the need of the pancreas has to

[25] P-LAC01.14 Audit procedure for liver HU status for pediatric patients, rephrased by P-LAC06.20, implemented April 2021
[26] P-LAC 01.18 HU liver criteria – Audit procedure implemented July,9 2018
[27] RLAC05.09 ELIAC meeting October 14, 2009
[28] RLAC05.09 ELIAC meeting October 14, 2009
[29] Agreed on in ELIAC meeting July 7, 2013
[30] Confirmed in ELAC meeting August 31, 2005.

be included. The request will be reviewed by one liver auditor and one intestine auditor. In case of a split decision an intestine specialist from the intestine auditor group will be asked as third auditor. Notification of the request will be made to the EPAC.

In case of an ACO request for multivisceral transplantations or modified multivisceral transplantations (including intestine and pancreas) with need of the pancreas for endocrine reasons, the request will be reviewed by one liver auditor, one intestine and one liver auditor[31].

5.2.2.1 ACO audit

The corresponding ACO forms (see Forms at www.eurotransplant.org) must be completed on all items with a complete and appropriate documentation and justification written in the English language and has to be sent back to the ET duty desk. The request is then forwarded to one member of the ELIAC (liver, intestine) and, depending on the other organ(s) and request type, one member of this organ-specific advisory committee(s) (pancreas [EPAC], thoracic [EThAC]). Both auditors must be from outside the requesting country and will be given 24 hours to reach a unanimous decision. In case of a split discission, a third member will decide on the approval or denial of the ACO request.

A remote center cannot assign status ACO in ENIS.

In case a center has entered in ENIS that they have no capacity for transplantation, ACO patients will still receive the offer.

5.2.3 Transplantable (T), elective pediatric patient

Pediatric patients are patients younger than 18 years of age. All liver matches consider patients younger than 18 years of age as pediatric patients in the corresponding match tiers (T/HU).

Pediatric patients accumulate pediatric MELD points.
In non-German countries, the pediatric MELD score accumulates until the 18th birthday. In Germany the pediatric MELD score is accumulated until the 16th birthday as stated by the German Richtlinie.

All pediatric patients registered on the liver waiting list enter MELD and PELD data (albumin), the latter only for scientific purposes. In the allocation, only the MELD types will be considered[32].

5.2.3.1 Pediatric patients <12 years

All patients <12 years of age are eligible for an initial pediatric MELD equivalent to 35%[33] probability of 3-month mortality on the waiting list.

5.2.3.2 Upgrade of pediatric MELD Pediatric patients <12 years

If a patient <12 years of age with a pediatric MELD was not transplanted within 90

[31] R-LAC07.16 Intestine – ACO status request including pancreas for anatomical reasons, implemented September 12, 2023
[32] RLAC03.05 of the PELD consensus meeting July 2005, approved by ELAC in August 2005 and ET Board in October 2005.
[33] In RLAC04.09 implemented on the 6th of December 2009 was stated that pediatric patients <12 years of age should get a higher pediatric Meld in order to lower the average waiting time.

days, then this pediatric MELD is automatically upgraded, without the need for an active reconfirmation by the center. The upgrade equals standard an additional 15% increase in probability of 3-month mortality on the waiting list

This procedure will be performed at the end of each 90-day cycle until transplantation or removal from the waiting list.

5.2.3.3 Pediatric patients ≥12 <18 years

All patients ≥12 <18 years of age (<16 years of age for Germany) are eligible for an initial pediatric MELD equivalent to 15%[34] probability of 3-month mortality on the waiting list.

5.2.3.4 Upgrade of pediatric MELD Pediatric patients ≥12 <18 years

If a patient ≥12 <18 years of age (<16 years of age for Germany) with a pediatric MELD was not transplanted within 90 days, then this pediatric MELD is automatically upgraded, without the need for an active reconfirmation by the center. The upgrade is a 10% increase in probability of 3-month mortality on the waiting list.

This procedure will be performed at the end of each 90-day cycle until transplantation or removal from the waiting list.

5.2.3.5 Pediatric patients turning 18 years on the waiting list

Pediatric patients registered younger than 18 years (<16 years of age for Germany), that turn 18 years (16 years for Germany) still awaiting transplantation, will have their (upgraded) pediatric MELD frozen at the level that it was when turning 18; no further automated upgrades are performed.

5.2.3.6 lab MELD and pediatric MELD

In addition to the pediatric MELD, patients <18 years of age (<16 years of age for Germany) are expected to have their lab MELD recertified according to the recertification schedule; urgency and country-specific rules apply.

If, in a matching procedure, a lab MELD is lower than the pediatric MELD, then the pediatric MELD is used.

If, in a matching procedure, a lab MELD is higher than the pediatric MELD, then the lab MELD is used.

5.2.3.7 Pediatric SE and reaching of age threshold

Some pediatric SE know an age threshold:
PH1 (Oxalosis) <1yr,
biliary atresia <2yr,.

If a pediatric patient with one of these SE reaches the age threshold, the exceptional MELD is frozen at the time the patient reaches the age threshold. This frozen exceptional MELD is kept until transplantation.

[34] In the discussion leading to RLAC03.05 it was stated that pediatric patients should at least not be disadvantaged with regard to HCC patients. The original proposal proposed 15% equivalent, changed to 10% assuming that HCC should be lowered to 10%. As a matter of fact, the bonus for HCC has never been lowered to 10%. Therefore, 15% should be maintained for children.

5.2.4 Transplantable (T), elective adult patient

Adult patients are patients 18 years of age (16 years of age for Germany) or older. Patients are stratified by lab MELD or exceptional MELD (or frozen MELD in case of registration on the waiting list in pediatric age), respectively, in descending order; urgency and country-specific rules apply.

Patients 18 years of age or older (16 years of age or older for Germany) should have the lab MELD recertified according to the recertification schedule.

5.2.5 Not Transplantable (NT)

Patients temporarily not transplantable (NT) should be placed in status NT. Time spent in NT is not limited. Patients in NT do not accumulate MELD-specific waiting time. Previously accumulated total and MELD-specific waiting time is retained in NT.

Patients appear on the national waiting list without MELD scores and are not selected in matching procedures.

MELD-specific waiting time counters start again once a patient is placed back in status transplantable (T).

5.2.5.1 Recertification and reconfirmation in NT

Patients in NT should have their lab MELD recertified according to the recertification schedule; urgency-specific rules apply.

Voluntary updates or scheduled recertifications of lab MELD do not result in the reactivation of a patient.

Patients with an exceptional MELD should have their exceptional MELD reconfirmed before the end of the 90-day period; country-specific rules apply.

5.2.5.2 Reactivation after NT

A patient is reactivated by assigning the transplantable (T) status. If a patient is placed back in an active status, then the last (un)recertified lab MELD or exceptional MELD is used in the matching.

5.3 ELAS - general

Selection and ranking of patients is based on medical urgency, AB0 blood group rules, donor weight, ENIS allocation profile, waiting time and donor region; country-specific rules apply.

5.3.1 Medical Urgency

Patients to be considered in the matching are patients who have a status different from NT and are transplantable with:
- urgency HU or ACO or T status;
- a valid ((un)recertified) lab MELD;
- a valid (upgraded) exceptional MELD;
- a valid (upgraded) pediatric MELD.

5.3.2 ENIS allocation profile

A transplant center must specify for each patient an ENIS center- or patient-specific allocation profile, respectively.

It is in the transplant center's responsibility to update the profile depending on the patient's requirements.

This allocation profile includes the option to accept a marginal liver. The liver donor will be marginal at registration if one of the following criteria is met:
- Donor age > 65 yrs
- ICU stay with ventilation > 7 days;
- BMI >30;
- Steatotic liver > 40%;
- Serum Sodium > 165 mmol/l;
- SGPT > 105 U/l;
- SGOT > 90 U/l;
- Serum Bilirubin > 3 mg/dl.

For patients with the HU liver status, the allocation profile items *age* and *weight* remain applicable on the match. Other allocation profile items will not be taken into account in the HU status.

5.3.3 General waiting time counter

After registration of a patient in an active urgency, the general waiting time counter starts. Every day spent in any active urgency HU or T counts towards the general waiting time; waiting time is counted in days and is not limited.

5.3.4 Urgency-specific waiting timer counters HU/ACO

Urgency HU and status ACO have an urgency-specific waiting time counter. Waiting time is counted starting on the most recent date of the start of the current HU/ACO period. The longest waiting HU/ACO patient is ranked first within the urgency-specific group.

5.3.5 Patients with equal MELD score

If two or more T patients have the same MELD score, i.e. lab MELD or exceptional MELD, respectively, then waiting time is used to further stratify these patients. Calculation of waiting time is performed each time an individual patient participates in a matching procedure.

Waiting time counted towards stratification is composed of time [d] spent:

- in the current MELD;
- previously higher lab MELD or exceptional MELD,
- previously in HU.

Waiting time in the previous higher lab MELD or exceptional MELD is only counted when there is no downgrade or lower MELD in between.

The patient with the longest waiting time according to this calculation is ranked first.

5.3.5.1 Example

A waiting list with more than one patient with the same MELD score could look like this:

Patient	MELD	Waiting days current MELD	Waiting days previous MELD, by score
A	25	2d	2d MELD 27
B	26	1d	34d MELD 22
C	18	30d	2d MELD 20
D	25	6d	None
E	18	30d	50d MELD 8
F	25	2d	3d MELD 26
G	12	85d	90d MELD 7

A match list at any point in time would then look like the following:

Patient	MELD	Waiting days current MELD	Waiting days previous MELD, by score
B	26	1d	34d MELD 22
D	25	6d	None
F	25	2d	3d MELD 26
A	25	2d	2d MELD 27
C	18	30d	2d MELD 20
E	18	30d	50d MELD 8
G	12	85d	90d MELD 7

5.3.6 Region

Countries within ET can choose to create sub regions within this country. Regions can be of influence in the allocation.

5.3.6.1 Germany

If two or more German T patients have the same lab MELD or exceptional MELD, respectively, then all patients from transplant centers assigned to the one of the seven DSO donor regions are ranked before all other German patients from transplant centers from outside the donor region.

Within the groups, i.e. those patients inside and outside the donor region are then again sorted by their accrued waiting time according to ET definitions (see 5.3.5).

5.3.6.1.1 German regions

Donor region	Transplant center
GBWOR	Heidelberg (GDBD), Tübingen (GTU)
GBYOR	München Großhadern (GML), München r.d. Isar (GMH), Nürnberg (GNB), Regensburg (GRB), Würzburg (GWZ)
GMIOR	Frankfurt (GFM), Mainz (GMZ)
GNDOR	Göttingen (GGO), Hamburg (GHG), Hannover (GHO), Kiel (GKI)
GNOOR	Berlin Charité (GBC), Rostock (GRO)
GNWOR	Aachen (GAK), Bonn (GBO), Essen (GES), Köln-Lindenthal (GKL), Köln-Merheim (GKM), Münster (GMN)
GOSOR	Jena (GJE), Leipzig (GLP), Magdeburg (GMB)

5.3.6.1.2 Match list examples

Waiting list

Patient	MELD	Waiting days current MELD	Waiting days previous MELD, by score	TXP center
A	25	2d	2d MELD 27	GJE
B	26	1d	34d MELD 22	GHG
C	18	30d	2d MELD 20	GHO
D	25	6d	None	GML
E	18	30d	50d MELD 8	GMB
F	25	2d	4d MELD 26	GFM
G	12	85d	90d MELD 7	GBO

1) Match list, donor from GOSOR

Patient	MELD	Waiting days current MELD	Waiting days previous MELD, by score	TXP center
B	26	1d	34d MELD 22	GHG
A	25	2d	2d MELD 27 3d MELD 15	GJE
F	25	2d	4d MELD 26	GFM
D	25	6d	None	GML
E	18	30d	50d MELD 8	GMB
C	18	30d	2d MELD 20 3d MELD 6	GHO
G	12	85d	90d MELD 7	GBO

2) Match list, donor from GMIOR

Patient	MELD	Waiting days current MELD	Waiting days previous MELD, by score	TXP center
B	26	1d	34d MELD 22	GHG
F	25	2d	4d MELD 26	GFM
D	25	6d	None	GML
A	25	2d	2d MELD 27 3d MELD 15	GJE
C	18	30d	2d MELD 20 3d MELD 6	GHO
E	18	30d	50d MELD 8	GMB
G	12	85d	90d MELD 7	GBO

5.3.7 AB0 blood group rules

In case the national allocation rules of a certain country contains standard center offers via the match, the standard blood group rules as described below apply. A patient can be selected from the match list and is therefore a patient with an active status and according to the blood group rules of the match.

In case no suitable blood group AB0-compatible patient (pediatric or adult) is found for a deceased donor <46 kg within Eurotransplant, this liver will be offered for transplantation in blood group AB0-incompatible children <1 year of age[35].

5.3.7.1 Pediatric donor (<46 kg)

5.3.7.1.1 HU pediatric (Full compatibility)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

5.3.7.1.2 HU adult (Compatibility type 1)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**B and O**

[35] *RLAC04.14 AB0-incompatible liver offers for pediatric recipients <1 year if no suitable AB0-compatible recipient can be found*, implemented as of May 16, 2017

5.3.7.1.3 ACO adult & pediatric (Full compatibility)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

5.3.7.1.4 T pediatric

AB0 identical (before Full compatibility)

Donor blood group	Eligible patients
A	**A (and AB)**
B	**B (and AB)**
AB	**AB**
O	**O (A, B, AB)**

5.3.7.1.5 T adult, MELD ≥30 (Compatibility type 1)

Donor blood group	Eligible patients
A	A and AB
B	B and AB
AB	AB
O	B and O

In the matching procedure this rule applies to:
all national ET patients with respect to the ET donor country based on the (exceptional) MELD;
all international ET patients with respect to the ET donor country based on the (un)recertified lab MELD;
all international ET patients with respect to non-ET donor countries based on the (un)recertified lab MELD.

5.3.7.1.6 T adult, MELD <30 (Compatibility type 2)

Donor blood group	Eligible patients
A	A and AB
B	B and AB
AB	AB
O	O

5.3.7.1.7 T adult, all MELD scores (Full compatibility)

Donor blood group	Eligible patients
A	A and AB
B	B and AB
AB	AB
O	A, B, AB and O

In the matching procedure this rule applies to:
all national ET patients with respect to the (non-German) ET donor country based on the (exceptional) MELD. See paragraph Allocation algorithm.

5.3.7.2 Adult donor (≥46 kg)

5.3.7.2.1 HU adult & pediatric (Compatibility type 1)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**B and O**

5.3.7.2.2 ACO adult & pediatric (Full compatibility)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

5.3.7.2.3 T adult & pediatric, MELD ≥30 (Compatibility type 1)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**B and O**

In the matching procedure this rule applies to:
all national ET patients with respect to the ET donor country based on the (exceptional) MELD;
all international ET patients with respect to the ET donor country based on the (un)recertified lab MELD;
all international ET patients with respect to non-ET donor countries based on the (un)recertified lab MELD.

5.3.7.2.4 T adult & pediatric, MELD <30 (Compatibility type 2)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**O**

In the matching procedure this rule applies to:
all national ET patients with respect to the ET donor country based on the (exceptional) MELD;
all international ET patients with respect to the ET donor country based on the (un)recertified lab MELD;
all international ET patients with respect to non-ET donor countries based on the (un)recertified lab MELD.

5.3.7.2.5 T adult & pediatric, all MELD scores (Full compatibility, non-German countries only)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

In the matching procedure this rule applies to:
all national ET patients with respect to the (non-German) ET donor country based on the (exceptional) MELD. See paragraph Allocation algorithm.

5.3.7.3 2nd Split, adult & pediatric (Full compatibility)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

5.3.7.4 Slovenia, adult T patients (Full compatibility)

Donor blood group	Eligible patients
A	**A and AB**
B	**B and AB**
AB	**AB**
O	**A, B, AB and O**

5.3.8 Split liver transplantation (SLT)

Suitable post-mortem livers should be split if possible. A transplant center accepting the initial ELAS whole liver offer can decide to split the liver and is then defined as the splitting center.

The splitting center is obliged to report this "intent to split" back to the ET duty desk at the time of accepting the whole liver offer. The center must report:

- which split-liver graft (LLS vs. eRL) is to be transplanted and which one is offered to ET;
- the splitting technique, i.e. in situ vs. ex situ;
- the location where the splitting procedure will be performed (transplant center, donor hospital, 2nd split transplant center);
- whether the splitting center has a suitable patient for the 2nd split in case of rescue allocation;
- whether the 1st split patient is suitable for a whole liver graft if the splitting cannot be performed or if a reduced size transplantation is performed.

For the allocation and national deviations, see paragraph Allocation algorithm.

5.3.8.1 50/50-rule

This rule is intended to increase awareness for SLT in Eurotransplant and to document a transplant centers intention to split at the time of a post-mortem whole liver offer.

Each liver from a post-mortem donor who meets the conditions ≥50 kg body weight **and** ≤ 50 years of age is considered a potential split-liver donor. The ET duty officers will ask the transplant center receiving a whole liver offer from this donor whether a split procedure is considered. The transplant center's decision will then be documented. If a transplant center does not consider a split procedure, a reason must be given. The transplant center's intention to split does not oblige the center to perform the procedure after receiving the whole liver for transplant.

5.3.8.2 Splitting not possible

If a splitting procedure is not possible, the whole liver:

- can be used for a reduced size liver transplantation;
- can be transplanted as a whole liver into the initially selected liver patient for who the split was planned, if he had also been eligible for this whole liver according to the ELAS match list;
- is offered to the first eligible whole liver patient on the initial whole liver ELAS match list if the initially selected patient is not eligible for a whole liver.

5.3.9 Domino liver transplantation

If a post-mortem donor liver is transplanted in a patient whose primary disease is a non-cirrhotic metabolic disorder, then this patient's liver could be used for a consecutive, second transplant. The decision to report a domino liver donor is made by the center of this patient.

The patient of the first post-mortem liver is then considered a "living donor".

A patient for this domino liver can be selected from the center's own waiting list. If no local patient is available, then this domino liver will be allocated through ELAS to patients from the waiting list selected according to their patient profile.

5.3.9.1 Deviant national regulations

5.3.9.1.1 **Germany**

According to the German law on transplantation (Transplantationsgesetz (TPG)), organs from a Domino donor are offered by the ET duty desk in a patient-oriented fashion with the help of the center- or patient-specific allocation profile in the ELAS liver match list (*Modifiziertes Vermittlungsverfahren*[36]*).*

[36] Richtlinien zur Organtransplantation gemäß §16 TPG, Access via www.baek.de on June 1, 2004

5.3.10 Non-heart-beating liver transplantation

Livers from non-heart-beating donors (DCD) may only be reported to and will only be allocated by Eurotransplant if the family of the donor has consented to donation.

5.3.10.1 Deviant national regulations

5.3.10.1.1 Austria

A liver from a DCD donor is allocated in a center-based fashion as for post-mortem heart-beating donors.

5.3.10.1.2 Belgium

A liver from a DCD donor is regarded to be an extended criteria donor (ECD) organ. The liver is offered in a center-based fashion, allowing the center to choose a suitable patient from its own waiting list:
first to the donor center,
then to the other Belgian centers following the match list.
In case of a pediatric donor standard allocation sequence is adhered to (see 5.3.14 Allocation algorithm pediatric donor (<46 kg) non-German countries) with the inclusion of center offers.
E.g. In case of a Belgian pediatric donor:
first a center offer is made to the donor center for pediatric and adult patients,
then center offers to all other national pediatric transplant centers,
then center offers to all other national adult centers.

Livers from Belgian DCD donor are not allocated to non-Belgian patients resulting from the ‘obligation to offer rule’

5.3.10.1.3 Croatia

Organs from a DCD donor must not be procured and/or allocated in Croatia.
DCD donor organs from outside Croatia must not be allocated and/or transplanted in Croatia.

5.3.10.1.4 Germany

According to the German law on transplantation (Transplantationsgesetz (TPG)), organs from a DCD donor must not be procured and/or allocated in Germany.

DCD donor organs from outside Germany must not be allocated and/or transplanted in Germany.

5.3.10.1.5 The Netherlands

The donor may be reported to ET no sooner than the planned switch off is known. If the donor is reported to ET, the Liver allocation can start immediately.

A liver from a DCD donor up until the age of 60 is allocated in a patient-oriented fashion as for post-mortem heart-beating donors.

For Dutch DCD donors aged 61 and older (DCD III and euthanasia). The Dutch liver transplant centers receive center offers that are incorporated into the match, based on a rotation schedule.[37]

Livers from Dutch DCD donor are not allocated to non-Dutch patients resulting from the 'obligation to offer rule'.

5.3.11 Kidney after other organ bonus

In addition to the option of performing a simultaneous liver-kidney transplant the option of transplanting the liver first and the kidney at a later time (i.e. a kidney-after liver transplant) is possible in selected cases. Bonus points for the kidney waiting list can be obtained. In particular this option is preferred in case of a hepatorenal syndrome. More details can be found in the Kidney manual.

5.3.12 Requirements

The minimum of standard vessels in the toolkit in case of separate transplantation of liver, pancreas and intestine for transplantation should be:

- Intestine: iliac vessels (artery and vein) and bifurcation
- Pancreas: iliac vessels (artery and vein) and bifurcation
- Liver: common hepatic artery, celiac trunk
- Cannulation in the donor should be done at the level of the aorta

In case all three organs are going to be procured the liver center has to be informed about the limitation in the toolkit at time of acceptance[38].

37 Requested by LOL Netherlands November 2024

38 Policy P-LAC10.16, result of the Eurotransplant Intestine Allocation Consensus Meeting June 22, 2016

5.4 ELAS - allocation algorithms

5.4.1 Basic allocation principle

Regular allocation is patient-oriented, i.e. organ offers are made to transplant centers for one patient at a time.

5.4.1.1 International allocation between ET countries

If a post-mortem donor organ cannot be allocated in the donor country, except in HU/ACO (see 5.4.2, 5.4.3) and obligation (see 5.4.5.2.1) patients, then the organ is offered to the other ET countries. Allocation is according to the international match list.

The basis for stratification on the international match list is each patient's lab MELD, i.e. either the calculated or downgraded lab MELD. (N)SE exceptional MELD are not considered in the international match.

As an exception, patients with a pediatric MELD maintain their pediatric MELD in the international allocation.

5.4.1.2 Deviant national definitions

5.4.1.2.1 Austria

Organ offers from Austrian donors are center-offers for the donor center or the assigned center. If a liver can't be allocated in the donor or assigned region, ET shall offer the liver patient-oriented according to the match list[39].
Donor organs resulting from the obligation-to-offer rule are assigned to an Austrian center and are defined as local donors, thus center offers.

In case of a center offer, patients can be selected according to the blood group rules on the match list.

Before allocating a donor to a suitable patient, Austrian centers must inform at the ET duty desk whether there are suitable HU and/or ACO patients in the non-Austrian ET region. In case of suitable HU and/or ACO patients this organ(s) must first be offered to ET. If the organ offer is not accepted for the respective HU and/or ACO patient, then the offer goes back to the donor center.

5.4.1.2.1.1 Austrian regions

Austria knows 3 regions comprising the transplant centers: Innsbruck (AIB), Graz (AGA) and Vienna (AWG).

[39] Conclusions of the meeting of the Austrian liver transplant centers, 18.10.2007 St Wolfgang, Annual Meeting of the Austrian Transplant Society.

5.4.1.2.1.2 Austrian free regions

Livers reported from the so-called Austrian free regions, i.e. regions reporting donors without a liver transplant program (Kärnten (AKT), Ober-Österreich (AOx)), are allocated to one of the three Austrian liver transplant programs.
Ranking of centers is based on the so-called stochastic center queue.

5.4.1.2.2 Belgium

Organs are offered according to the Belgian law on transplantation, i.e. patients that are listed as follows

first to Belgian citizens or those that have their permanent address in Belgium,
then to ET citizens or those that have their permanent address in ET,
then to non-ET citizens listed in Belgium that fulfill none of the above criteria.

5.4.1.2.3 Croatia

Organ offers from Croatian donors are center offers; the center is elected by the Ministry of Health and Social Welfare. Donor organs resulting from the obligation-to-offer rule are assigned to the ministry of Health and Social Welfare and are defined as local donors, thus center offers.

In case of a center offer, patients can be selected according to the blood group rules on the match list.

Before allocating a donor to a suitable patient, the ministry of Health and Social Welfare must inform at the ET duty desk whether there are suitable HU and/or ACO patients in the non-Croatian ET region. In case of suitable HU and/or ACO patients this organ must first be offered to ET. If the organ offer is not accepted for the respective HU and/or ACO patient, then the offer goes back to the Ministry of Health and Social Welfare.

5.4.2 Allocation algorithm pediatric donor (<46 kg) non-German countries[40]

Livers from pediatric donors should not be used in patients if the donor-to-patient weight ratio is ≥0.5[41].

first, to pediatric HU patients (Full compatibility)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to adult HU patients (Compatibility type 1)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to pediatric ACO multi-organ patients (Full compatibility)
(if > 1 ACO patient, they appear in order of waiting time in CO)

then, to adult ACO multi-organ patients (Full compatibility)
(if > 1 ACO patient, they appear in order of waiting time in CO)

then, to pediatric patients in open obligation countries/centers
ranked by MELD; (AB0-identical before Full compatibility)

then, to pediatric patients in the donor country
ranked by MELD; (AB0-identical before Full compatibility)

then, to adult patients <55kg in open obligation countries/centers
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2) (See Chapter Blood Group Rules)

then, to adult patients ≥55kg in open obligation countries/centers
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients <55kg in the donor country
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients ≥55kg in the donor country
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients of all weights in the donor country
ranked by MELD; Full compatibility

then, to pediatric patients in the other ET countries
ranked by MELD; (AB0-identical before Full compatibility)

then, to adult patients <55kg in the other ET countries
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients ≥55kg in the other ET countries
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

[40] According to Recommendation R-LAC 05.14. Implemented June 20, 2015
[41] Recommendation based on: Adam R, Castaing D, Bismuth H. Transplantation of small donor livers in adult recipients. Transplantation Proceedings 1993; 25: 1105-1106.

Allocation algorithm pediatric donor non-German countries	Blood group rules
HU pediatric	Full compatibility
HU adult	Compatibility type 1
ACO pediatric	Full compatibility
ACO adult	Full compatibility
pediatric obligation	AB0-identical before Full compatibility
pediatric recipients donor country	AB0-identical before Full compatibility
adult obligation (<55kg before ≥55kg)	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
adult recipients donor country <55kg	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
adult recipients donor country ≥55kg	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
adult recipients donor country	All MELD scores: Full compatibility
pediatric recipients international	AB0-identical before Full compatibility
adult recipients international <55kg	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
adult recipients international ≥55kg	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
Slovenian donors	Recipients <55kg before ≥55kg, national adult and pediatric T patients Full compatibility

The above scheme follows the national allocation agreements for center based or patient based offers.

5.4.2.1 Allocation algorithm pediatric donor (<46 kg) Germany

first, to pediatric HU patients (Full compatibility)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to adult HU patients (Compatibility type 1)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to pediatric ACO multi-organ patients (Full compatibility)
(if > 1 ACO patient, they appear in order of waiting time in CO)

then, to adult ACO multi-organ patients (Full compatibility)
(if > 1 ACO patient, they appear in order of waiting time in CO)

then, to pediatric patients in open obligation countries/centers
ranked by MELD; (AB0-identical before Full compatibility)

then, to pediatric patients in the donor country
ranked by region and MELD[42]; (AB0-identical before Full compatibility)

then, to pediatric patients in the other ET countries
ranked by MELD; (AB0-identical before Full compatibility)

then, to adult patients in open obligation countries/centers
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients in the donor country
ranked by region and MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to adult patients in the other ET countries
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

[42] Richtlinien zur Organtransplantation gemäß §16 TPG, accessed via www.baek.de on December 4, 2006

5.4.3 Allocation algorithm adult donor (≥46 kg) non-German countries

first, to HU patients (pediatric & adult) (Compatibility type 1)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to ACO multi-organ patients (pediatric & adult) (Full compatibility)
(if > 1 ACO patient, they appear in order of waiting time in ACO)

then, to pediatric & adult patients in open obligation countries/centers
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to pediatric & adult patients in the donor country
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2), before all MELD scores (Full compatibility).

then, to pediatric & adult patients in other ET countries
ranked by MELD; MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

Allocation algorithm Adult donor non-German countries	**Blood group rules**
HU (pediatric and adult)	Compatibility type 1
ACO (pediatric and adult)	Full compatibility
obligation (pediatric and adult)	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
donor country (pediatric and adult)	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
donor country (pediatric and adult)	All MELD scores: Full compatibility
international (pediatric and adult)	MELD≥30: Compatibility type 1 before MELD<30: Compatibility type 2
Slovenian donors	National adult and pediatric T patients Full compatibility

5.4.3.1 Allocation algorithm adult donor (≥46 kg) Germany

first, to HU patients (pediatric & adult)
(if > 1 HU patient, they appear in order of waiting time in HU)

then, to ACO multi-organ patients (pediatric & adult)
(if > 1 ACO patient, they appear in order of waiting time in ACO)

then, to pediatric & adult patients in open obligation countries/centers
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

then, to pediatric & adult patients in the donor country
ranked by region and MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2).

then, to pediatric & adult patients in other ET countries
ranked by MELD: MELD ≥30 (Compatibility type 1) before MELD <30 (Compatibility type 2)

5.4.4 Split liver allocation algorithm

One split must be transplanted to the patient initially selected by ELAS and for which the splitting center accepted the whole liver.

The allocation algorithm for the **second** split is as follows:

first, locally, a suitable patient is chosen by the transplant center from its own waiting list.
then, suitable patients selected by ELAS split liver match, first
regionally, then
nationally, then
internationally.

The second split can, e.g. due to logistical or organ-specific reasons, be allocated in centers within close proximity to the splitting center with the help of the so-called rescue allocation.

If, ultimately, the whole liver cannot be split, the patient initially selected by the ELAS whole liver match (patient that initially accepted the liver for split) receives the whole liver graft. The accepting center of the second split will be informed that the splitting procedure will not be performed and the offer to their patient is therefore withdrawn.
If the initial patient is not eligible for a whole liver graft, e.g. due to a size mismatch, the HU patients that newly received the HU status during this allocation procedure will receive the offer of the whole liver, if applicable.
In case the liver is not accepted for the above mentioned HU patient, the liver will be offered to the patient that accepted the back-up offer for whole liver. Thereafter, the allocation will proceed according to standard procedure.

5.4.4.1 Deviant national regulations

5.4.4.1.1 Germany[43]

5.4.4.1.1.1 Splitting for left lateral segment & extended right lobe

5.4.4.1.1.1.1 Extended right lobe as second Split

The patient-oriented allocation algorithm for the **second** split is as follows:

first, to HU patients (pediatric & adult)
then, nationally, suitable patients selected by ELAS split liver match
ranked by region and MELD;
then, internationally, suitable patients selected by ELAS split liver match
ranked by MELD.

If, ultimately, the whole liver cannot be split, then the patient initially selected by the ELAS whole liver match receives the whole liver graft. If this patient is not eligible for a whole liver graft, e.g. due to a size mismatch, then the liver is offered to the first following patient on the ELAS whole liver match eligible for a whole liver graft.

[43] Richtlinien zur Organtransplantation gemäß §16 TPG, Access via www.baek.de on December 4, 2006.

5.4.4.1.1.1.2 Left lateral segment as second Split

The allocation algorithm for the **second** split is as follows:

first, to HU patients (pediatric & adult)
then, locally, a suitable patient is chosen by the transplant center from its own waiting list.
then, nationally, suitable patients selected by ELAS split liver match ranked by region and MELD;
then, internationally, suitable patients selected by ELAS split liver match ranked by MELD.

If, ultimately, the whole liver cannot be split, then the patient initially selected by the ELAS whole liver match receives the whole liver graft. If this patient is not eligible for a whole liver graft, e.g. due to a size mismatch, then the liver is offered to the first following patient on the ELAS whole liver match eligible for a whole liver graft.

5.4.4.1.1.2 Splitting for left lobe & right lobe

The rescue allocation algorithm for the **second** split is as follows:

first, locally, a suitable patient is chosen by the transplant center from its own waiting list.
then, regionally, suitable patients selected by ELAS split liver match.
then, nationally, suitable patients selected by ELAS split liver match.
then, internationally, suitable patients selected by ELAS split liver match.

If, ultimately, the whole liver cannot be split, then the patient initially selected by the ELAS whole liver match receives the whole liver graft. If this patient is not eligible for a whole liver graft, e.g. due to a size mismatch, then the liver is offered to the first following patient on the ELAS whole liver match eligible for a whole liver graft.

5.4.5 Obligation to offer

5.4.5.1 Generating an obligation

An ‘obligation to offer’ is generated, if a liver from a donor outside the transplant center’s country is transplanted into a patient in urgency HU or ACO.

In case a liver is allocated to a patient outside the donor country within ET for a HU or ACO patient and later it turns out that this patient is not-transplantable with this liver but the liver is transplanted into an elective patient in the patient country via Extended or rescue allocation, this shall nevertheless open up an obligation to send back a liver from the patient country to the donor country.[44]

A receiving country has then an “obligation to offer” the next available liver in the same blood group to be able to close the obligation.

Open obligations in multiple countries can be linked.

5.4.5.2 Closing an obligation

Only if an ‘obligation-to-offer’ liver is offered to and transplanted in the former donor country, will an obligation be closed.

No time limit applies to obligations, they remain open until they are closed.

5.4.5.2.1 Allocation of obligation livers

In case a liver, resulting from an obligation, is offered to a center/country, then this liver is considered to be a local/national liver. As such, all local/national rules apply and the lab MELD or exceptional MELD will be applicable.

5.4.5.2.2 Order of closing an obligation

In case of >1 open obligations, offers will first go to eligible patients from the country with the oldest open obligation, i.e. the obligation that has been created first. Offers are then made in descending order to the second oldest open obligation etc.

Example:
A donor country/center has 3 open obligations in the same blood group:
1 to the Netherlands (since February 14, 2005),
1 to Germany (since March 20, 2005) and
2 to Belgium (one since January 5, 2005, one since April 10, 2005).

Closing of open obligations will be in the following order:
First Belgian patients,
then Dutch patients,
then German patients,
then Belgian patients.

[44] RLAC02.10 implemented in Release 3, 2011

5.4.5.3 Deviant national definitions

5.4.5.3.1 **Austria**

In Austria, obligations are generated and closed on the basis of 'country to center' and 'center to country', respectively.

5.4.5.3.2 **Slovenia**

An obligation is created according to official rules. Closing of an *open obligation* can occur according to the following mutual agreement[45]:

AB0 blood group for closing an obligation
Slovenia is allowed to close an obligation AB0 compatible, i.e. not necessarily blood group identical.

Moment of closing an obligation
Slovenia can, in case of an own donor and an open obligation to another ET country, decide whether to close the obligation with that donor. If they decide not to close the obligation then this obligation remains open until the next donor and/or until it is closed.

5.4.5.3.3 **Netherlands**

An obligation from the Netherlands will not be redeemed with a DCD donor. Therefore the match of a DCD liver of a Dutch donor will not contain open obligations.

The creation of obligations will be according to the standard procedure (e.g. in case of accepted and transplantation for a HU patient this will result in an obligation)

5.4.5.3.4 **Belgium[46]**

An obligation from Belgium will not be redeemed with a DCD donor. Therefore the match of a DCD liver of a Belgian donor will not contain open obligations.

The creation of obligations will be according to the standard procedure (e.g. in case of accepted and transplantation for a HU patient this will result in an obligation)

[45] Officially agreed on in May 2004 and confirmed for prolongation in November 2004.
[46] Implemented September 2013 13028LAC13

5.5 Registration of elective (T) patients

In the course of the (re)registration of a patient on the liver waiting list centers must enter MELD data for calculation of lab MELD.

5.5.1 Quality assurance and data verification

5.5.1.1 All MELD scores

Renal replacement therapy
In case of renal replacement therapy the name of the responsible physician confirming the indication for this therapy must be filled out in the ENIS system or Meld application.[47]

For patients on renal replacement therapy, defined as having 2 or more dialysis treatments within the prior week, or patients who have received 24 hours of CVVHD within the prior week, the serum creatinine level will automatically be set to 4.0 mg/dl.[48]

Extracorporeal liver support
In case a patient is on extracorporeal liver support, the center may use the bilirubin and creatinine values measured most prior to the start of the extracorporeal liver support.[49]
This labMELD under extracorporeal liver support is valid for 7 days irrespective of the height of the labMELD. After 7 days, a re-confirmation can be made.
Extracorporeal liver support used to be described as MARS therapy, but since several systems are capable of providing liver support, the term MARS therapy is replaced by the more general term extracorporeal liver support as of 29-01-19. Renal replacement therapy is not considered to be extracorporeal liver support.

Vitamin K anatagonists
The INR value is only valid if no Vitamin K antagonists were administered within 2 weeks before determination of that INR value.
In case of Vitamin K antagonist therapy the last value prior to starting Vitamin K antagonists has to be used or the oral Vitamin K antagonists have to be stopped for at least two weeks to determine the current INR.
If no INR value is known at the time of data administration in the Eurotransplant system, a value of 1.00 will be used in the MELD score calculation.[50]

Direct oral anticoagulants (DOAC)
The INR is only valid if either no DOAC is used or any remaining anticoagulative effect of current use of DOAC has been ruled out.
If DOAC is used and anticoagulative effects are present an INR value of 1.00 will be used in the MELD score calculation[51]

Not measureable INR
In case the INR value needed for calculation of the labMELD is not measurable for a reason motivated by the treating physician, an INR equivalent (e.g. derived from the Quick) will be determined by an ELIAC auditor with the use of a conversion table, approved by the ELIAC, which is suitable for the respective coagulation test (different pharmaceuticals companies), that is used in the hospital.[52]

[47] R-LAC 01.12 Agreed on in January 2012 during the Board meeting implemented in the ENIS system and meld application.
[48] Agreed on textual adjustment March 2013 during ELIAC meeting
[49] R-LAC04.13 MARS Therapy, Implemented on Oct 27, 2016
[50] R-LAC 02.13.Implemented as mandatory for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, mandatory for Austria as of September 12, 2015, mandatory for Germany as of May 17, 2016.
[51] R-LAC01.23 - Medication with influence on the INR, implemented September 12, 2023
[52] P-LAC02.15 Not measureable INR

This policy is developed in order to facilitate the use of an INR value in cases in which the INR value of a patient cannot be measured. It is decided that in those motivated cases an ELIAC auditor will determine an INR equivalent for the Quick using a conversion table. Each pharmaceutical company that provides coagulation factors for clinical coagulation tests has a specific conversion table for Quick, PT and INR, that has been validated for their specific coagulation factors. Since the conversion tables can differ amongst companies and therefore amongst centers, the requesting liver transplant center will have to provide the ELIAC auditor with the conversion table as used by their laboratory. This conversion table will contain the ISI (International Sensitivity Index).

5.5.1.2 MELD 25+

Every patient that is registered on the waiting list with a calculated lab MELD 25+, i.e. no downgrades, will have to undergo a verification procedure.

MELD 25+ verification is performed every day. Upon registration of a patient with a lab MELD 25+, centers will immediately be informed that they have to send the original lab data to the ET medical administration.

All patients registered with lab MELD 25+ will be assigned the status pending with regard to their lab MELD. Centers will have to send the lab data before 08:00 the following day.

The ET medical administration will check:

- every incoming lab sheet for MELD 25+ patients on the day of registration of MELD 25+;
- every morning at 08:00 the day after registration with MELD 25+ whether all lab data for all MELD 25+ patients have been received.

During the status pending all registered patients participate in the match as if the lab MELD was valid, i.e. no patient is put at a disadvantage due to the audit.

5.5.1.2.1 No (lab) data provided

If no lab data was provided until the morning after registration with lab MELD 25+, then the lab MELD as entered on data entry will be declared invalid. The patient receives a comment in his MELD history explaining the decision.

The lab MELD will still appear in the individual's MELD history but he will not be counted in any procedure involving MELD-specific waiting time. Such is the case in matching procedures with two or more patients with the same MELD score.

If one request has been denied than any following request will be audited until the first accepted status was granted.

5.5.1.2.2 (Lab) data provided

If lab data was sent then the ET medical administration will check for consistency in the following:

- the data on the original lab sheet is not handwritten (except for the ET number of the patient).

- identity of the patient; name and date of birth
- sample date must not be older than defined in the recertification schedule;
- all lab values must be identical in ENIS and on the lab sheet.
- all lab values must be from the same sample.
- most recent available lab data must be used.

If lab data are consistent then the patient receives the approved status and the lab MELD is officially declared valid and will appear in the patients MELD history and is counted in procedures involving MELD-specific waiting time.

If lab data are inconsistent then the lab MELD will be declined. Only after inconsistencies were explained and necessary adaptations were performed will the patient receive the approved status and will the lab MELD be declared valid. The lab MELD then appears in the patients MELD history and is counted in procedures involving MELD-specific waiting time.

5.5.1.2.3 Transplantation with unverified lab MELD

As a patient with status pending participates in the allocation, he can be transplanted without verified lab values. If, after transplantation, verification of the original lab values shows the data to be inconsistent without explanation, then this case will be reported to the national authorities for further evaluation.

5.5.1.3 Lab Meld <25

For patients with a calculated lab Meld <25, audits will be performed every day and at random (Random audit).

Upon registration of a patient with a random audit, centers will immediately be informed that they have to send the original lab data to the ET medical administration.

All patients registered for the random audit will be assigned the status pending with regard to their lab MELD. Centers will have to send the lab data before 08:00 hrs the following day.

The ET medical administration will check:

- every incoming lab sheet for random audit patients on the day of the random audit;
- every morning at 08:00 hrs the day after the random audit whether all lab data for all random audit patients have been received.
- the data on the original lab sheet is not handwritten (except for the ET number of the patient).
- most recent available lab data must be used
- all lab values must be from the same sample.

During the status pending all registered patients participate in the match as if the lab MELD was valid, i.e. no patient is put at a disadvantage due to the random audit.

5.5.1.3.1 No lab data provided

If no lab data was provided until the morning after the random audit, then the lab MELD as entered on the random audit will be declared invalid. The patient receives a comment in his MELD history explaining the decision.

The lab MELD will still appear in the individual's MELD history but he will not be counted in any procedure involving MELD-specific waiting time. Such is the case in matching procedures with two or more patients with the same MELD score.

If one request has been denied than any following request will be audited until the first accepted status was granted.

5.5.1.3.2 Lab data provided

If lab data was sent then the ET medical administration will check for consistency in the following fields:

- identity of the patient;
- sample date must not be older than defined in the recertification schedule;
- all lab values must be identical in ENIS and on the lab sheet.
- all lab values must be from the same sample
- most recent available lab data must be used.

Note: Information on the lab sheet (patient identification and lab values) is not allowed to be handwritten (except for the ET number of the patient).

If lab data is consistent then the patient receives the approved status and the lab MELD is officially declared valid and will appear in the patients MELD history and is counted in procedures involving MELD-specific waiting time.

If lab data is inconsistent, then the center will be contacted to explain the inconsistency. Only after inconsistencies were explained and necessary adaptations were performed will the patient receive the approved status and will the lab MELD be officially declared valid. The lab MELD then appears in the patients MELD history and is counted in procedures involving MELD-specific waiting time.

5.5.1.3.3 Transplantation with unverified lab MELD

As a patient with status pending participates in the allocation, he can be transplanted without verified lab values. If, after transplantation, verification of the original lab values shows the data to be inconsistent without explanation, then this case will be reported to the national authorities for further evaluation.

5.5.2 Requests for higher priority

5.5.2.1 Request for HU

Centers can request a high urgency (HU) status for patients with acute liver failure (ALF) or those in need of an acute re-transplantation. Upon requesting of the HU status, the patient must have an active (T) waiting list status.
Handling of requests and auditing are manual procedures. Upgrading, i.e. change to HU status in ENIS is done manually at ET.

Patients accepted to HU have to continue their patient's recertification of lab MELD according to the regular schedule. Voluntary updates can also be performed.

A patient's HU status is <u>not</u> changed due to results from the either scheduled labMELD recertification or voluntary update, i.e. upgrade or downgrade.

5.5.2.1.1 HU and voluntary labMELD updates

If the lab MELD of a patient is voluntarily updated, this updated lab MELD will be stored in ENIS. Scheduled recertification is due according to the schedule applicable for this updated score.

5.5.2.1.2 HU and scheduled labMELD recertification

If a patient's labMELD is regularly recertified, this recertified lab MELD will be stored in ENIS. Scheduled recertification is due according to the schedule applicable for this recertified score.

If a patient is not recertified on time, the labMELD will be downgraded to MELD 6.

5.5.2.1.3 Change of HU to T

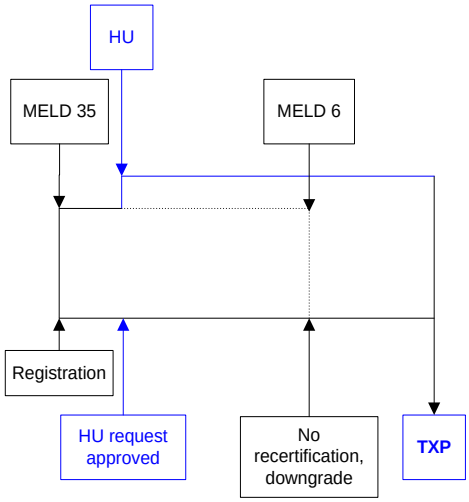
If the HU status is changed to T, then the current MELD is applied in the matching. Status HU can be changed by the center in the following way:

- transplantation (status FU);
- removal from the waiting list (status R);
- change to T with most recent (un)recertified lab MELD applied;
- change to status NT.

5.5.2.1.4 Examples

Example 1

Transplanted in HU with unrecertified lab MELD



HU patient reached scheduled lab MELD recertification, no recertification and lab MELD downgraded to MELD 6 ; HU maintained.

Example 2

Transplantation in unrecertified lab MELD.

HU patient reached scheduled lab MELD recertification, no recertification and lab MELD downgraded to MELD 6; HU maintained.HU patient improves and status is changed to T; current unrecertified lab MELD is applied.

5.5.2.2 Request for ACO

Centers can request status Approved Combined Organ (ACO) for patients in need of a combined liver and non-renal organ. Upon requesting of the ACO status the patient must have an active (T) waiting list status.
Handling of requests and auditing are manual procedures. Upgrading, i.e. change to ACO status in ENIS is done manually at ET.

Patients accepted to ACO have to continue their patient's recertification of MELD according to the regular schedule. Voluntary updates can also be performed.

A patient's ACO status is <u>not</u> changed due to results from the either scheduled recertification or voluntary update, i.e. upgrade or downgrade.

5.5.2.2.1 ACO and voluntary updates

If a patient is voluntarily updated, then this updated lab MELD will be stored in ENIS. Scheduled recertification is due according to the schedule applicable for this updated score.

5.5.2.2.2 ACO and scheduled recertification

If a patient is regularly recertified, then this recertified lab MELD will be stored in ENIS. Scheduled recertification is due according to the schedule applicable for this recertified score.

If a patient is not recertified on time then he will be MELD 6.

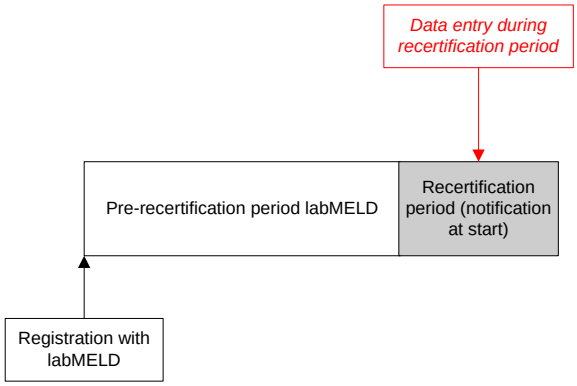
5.5.2.2.3 Change of ACO to T

If the ACO status is changed to T, then the current (un)recertified MELD is applied in the matching.

5.6 Recertification of patients

5.6.1 Scheduled recertification

Non-HU patients with their (downgrade) lab MELD applied in the matching have to be updated at scheduled intervals. Centers are notified of the start of the scheduled recertification period via the MELD-application.



Data must not be older than the specified expiry date at data entry. If lab values are older than allowed (see 5.1.2.1) then the data are not accepted; urgency and country-specific rules apply.

Transplant centers are responsible for the correctness of data entered to recertify the patients' MELD.

5.6.1.1 ET recertification schedule

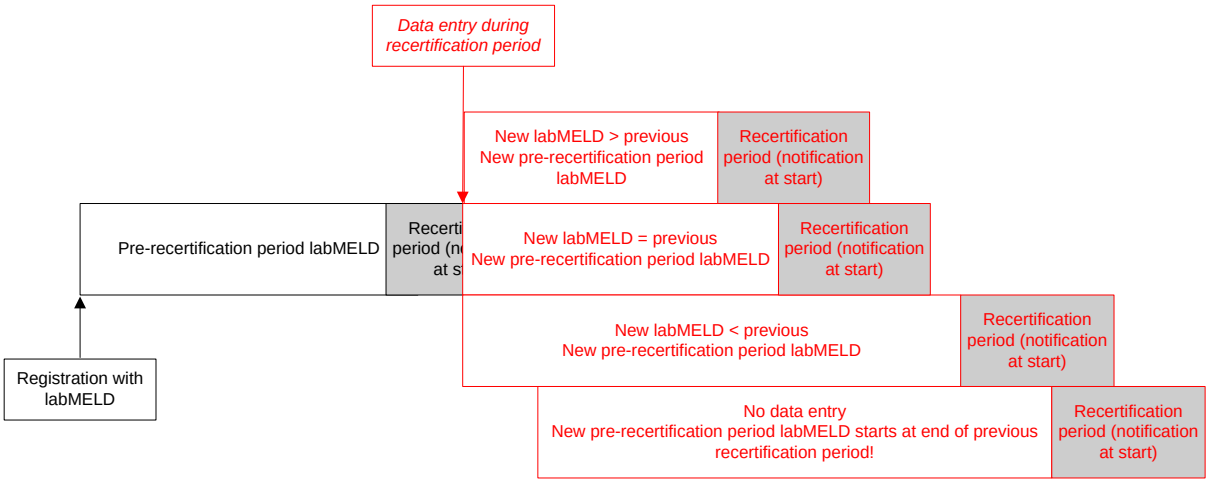
MELD	MELD expires after	Data entry before end of recertification period	Expiry date of lab values at data entry
MELD ≥25	7 d	48 h	not older than 48 h
MELD 19 - 24	30 d	7d	not older than 7 d
MELD 11- 18	90 d	14 d	not older than 14 d
MELD ≤10	365 d	30 d	not older than 30 d

5.6.1.2 Recertification results and consequences

If a patient's lab MELD is:

- equal to the previous lab MELD, then the patient is maintained in this lab MELD;
- higher than the previous lab MELD, then the patient is immediately upgraded to this higher score;
- lower than the previous lab MELD, then the patient is immediately downgraded to this lower score.

New recertification intervals immediately start at the moment of data entry during the scheduled recertification period. The length of the new interval is again determined by the recertified lab MELD.



5.6.1.2.1 No data received at recertification date[53]

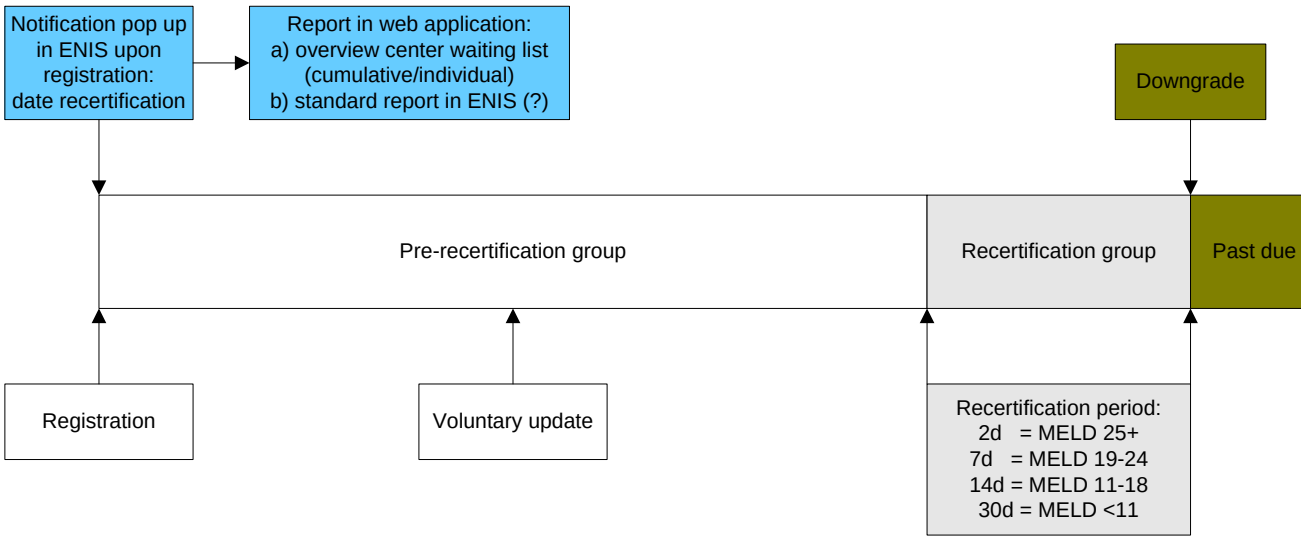
If a patient's lab MELD is not recertified during the scheduled recertification period, then the patient is downgraded to MELD 6 at the end of the scheduled recertification period.

[53] Decided on ELIAC meeting March 2013 according to German Richtlinien

5.6.1.3 Waiting list management lab MELD

All patients, i.e. those with lab MELD and with an exceptional MELD, must recertify their patients' lab MELD at set intervals (see regular recertification schedule).

ET supports remote users in their waiting list management by providing two electronic notifications and several reports.



5.6.1.3.1 Notifications

A notification appears during the registration cascade, after lab MELD is calculated and stored in ENIS, when a pop up window indicates for this registered patient:

- MELD score group (see recertification schedule);
- date and time of start of scheduled recertification period;
- date and time of end of scheduled recertification period, i.e. that a downgrade will be performed after the end of the period without recertification;

5.6.1.3.2 Waiting list overview

After registration of a patient on the waiting list, i.e. with an initial lab MELD, this patient will be added to a center's liver waiting list report.

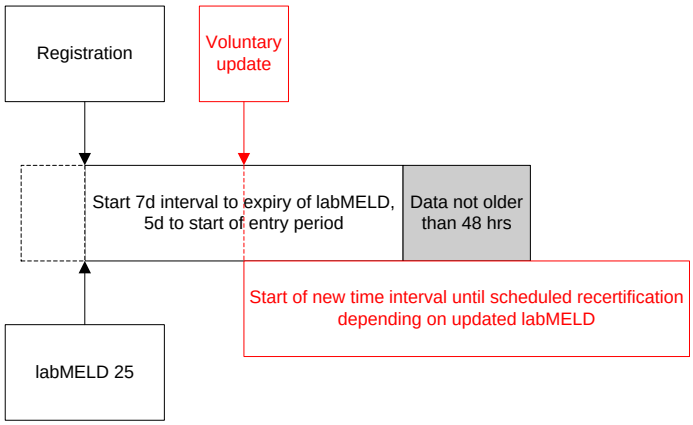
An overview of the center's waiting list will be accessible through the MELD web application that contains:

- a tool to sort the waiting list according to remote user wishes;
- request tool for (N)SE requests;
- information on pre-recertification, recertification and past due statuses of their patients;
- information on reconfirmation statuses of their patients;

5.6.2 Voluntary updates

5.6.2.1 lab MELD

A transplant center can update a patient's MELD voluntarily at any time between the start of the regular recertification interval and the start of the mandatory recertification period.



A higher lab MELD would improve this patient's chance for a timely transplantation. A lower lab MELD would prevent jeopardizing other patients' chances for a timely transplantation.

A patient's voluntarily updated lab MELD is applied in the matching.

The length of the time interval until the next scheduled recertification starts on the day of this voluntary update and is according to the regular recertification schedule.

5.6.2.2 Exceptional MELD

Patients with an SE/NSE exceptional MELD can have their exceptional MELD not voluntarily reconfirmed. The reconfirmation of an SE/NSE exceptional MELD can only be performed within 14 days before the end of the 90-day period.

5.6.2.3 Example

Patient	Current lab MELD	Expiry date of current lab MELD	Voluntarily updated lab MELD	New expiry date of updated lab MELD
A	8	x + 365 d	12	x + 90 d
B	15	x + 90 d	22	x + 30d
C	25	x + 7 d	26	x + 7 d
D	25	x + 7 d	22	x + 30 d
E	17	x + 90 d	10	x + 365 d

5.6.3 Not Transplantable (NT)

Patients temporarily not transplantable (NT) should be in status NT. In NT, no MELD-specific waiting time is accumulated; previous time is retained.

5.6.3.1 Example

Urgency changes	Date	Waiting days for matching[54] (total since registration)	Comment
MELD 14	01.01.2006	0	Initial registration
MELD 25	25.01.2006	24	Voluntary upgrade
MELD 26	24.02.2006	54	Scheduled recertification
NT	28.02.2006	58	
MELD 22	07.03.2006	58	Reactivation after NT
MELD 26	14.03.2006	65	Voluntary upgrade

5.6.3.2 Recertification schedules while in NT

Patients in NT fall under the rules for scheduled recertification, i.e. during NT lab MELD should be recertified. This is important as, upon reactivation, a patient's (un)certified lab MELD will be applied in matching procedures. Patients in NT can also be voluntarily updated.

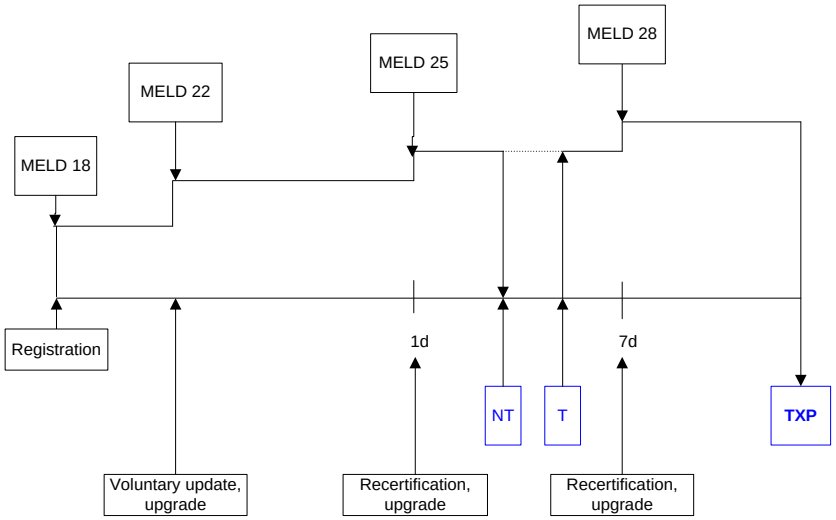
Once a score is updated they are stored and will initiate the start of a new recertification period depending on the height of this recertified or updated new MELD score.

Neither a scheduled recertification nor a voluntary update will result in the reactivation of a patient from NT to T.

[54] Number of days show difference between date of registration and date of urgency change, and in brackets the total number of days on waiting list, respectively.

5.6.3.3 Examples

5.6.3.3.1 No update or recertification during NT



Patient spends 2 days in NT (day 3-5) of his recertification interval in MELD 25. After reactivation this MELD score is used until scheduled recertification on day 7.

5.6.3.3.2 Downgrade after missed recertification during NT

Patient spends 12 days in NT (day 3-15). On day 7 he is not recertified and therefore downgraded to MELD 6. The new recertification interval starts on the day of the downgrade. Upon reactivation this patient is in the MELD 6 interval, and MELD 6 will be used for this patient.

5.6.3.3.3 Scheduled recertification during NT

Patient spends 10 days in NT (day 3-13). On day 7 he is recertified and upgraded to lab MELD 28. The new 7-day recertification interval starts on the day of the upgrade. Upon reactivation this patient is still in the MELD 28 interval, and MELD 28 will be used for this patient. After reactivation, on day 7 of his new recertification schedule, he is not recertified and therefore downgraded to MELD 6. The new recertification interval starts on the day of the downgrade.

5.6.3.3.4 Voluntary update and scheduled recertification during NT

Patient spends 10 days in NT (day 3-13). On day 5 of his MELD 25 interval he is voluntarily updated to lab MELD 28. On day 7 of his MELD 28 interval he is recertified and upgraded to lab MELD 30 with the new 7-day recertification interval starting that day. Upon reactivation this patient is in MELD 30, which will be used for this patient. After reactivation, on day 7 of his new recertification schedule, he is not recertified and therefore downgraded to MELD 6.

5.7 Registration of exceptional status

5.7.1 Request for exception

Patients whose disease severity is not adequately reflected by lab MELD can, at the initiative of the transplant center, be requested for an exceptional MELD, either during the initial registration or re-registration or at any point in time thereafter.

There are two different requests, i.e. one for so-called standard exception (SE) and those for non-standard exceptions (NSE).

5.7.1.1 Standard exception (SE)

All patients can be requested for an SE; disease and country-specific rules apply. Each country has its own list of defined SE (Standard exception (SE), stratified by disease) which contain:
diseases eligible for SE;
disease-specific SE criteria;
initial MELD equivalent assigned at time of approval;
time interval until upgrade and MELD equivalent upon upgrade.

Patients must fulfill country and disease-specific criteria before the exceptional SE exceptional MELD can be approved (see Addendum A - standard exception lists).

If the SE exceptional MELD was approved, then this status is granted for the duration of 90 days. Before the expiry of this 90-day period the SE status must be reconfirmed.

5.7.1.2 Non-standard exception (NSE)

Patients not eligible for an SE and not well stratified by their lab MELD can request a non-standard exception (NSE). They can request this either upon initial registration or at any time after registration; disease and country-specific rules apply[55].
For patients with diagnosis *E02 Cancers - Hepatocellular carcinoma and non-cirrhotic liver* and *E03 Cancers - Hepatocellular carcinoma - Fibrolamellar* the SE HCC is no longer applicable[56].
Guidelines for auditing a NSE request have been formulated during the HCC consensus meetings of 2019 and 2020. (See Auditor guidelines for NSE requests).

NSE patients are prospectively audited by a national audit group. Patients must be approved by the national audit group before the NSE exceptional MELD is granted.

The initial NSE exceptional MELD for non-German countries is equal to 10% equivalent of 3-month probability of death.
For Germany the Initial exceptional MELD is equal to 15% equivalent of 3-month probability of death (see Addendum B – MELD equivalents).

If the NSE exceptional MELD was approved, then this status is granted for the duration of 90 days. Before the expiry of this 90-day period the NSE status must be reconfirmed (except for Belgium and the Netherlands[57]).

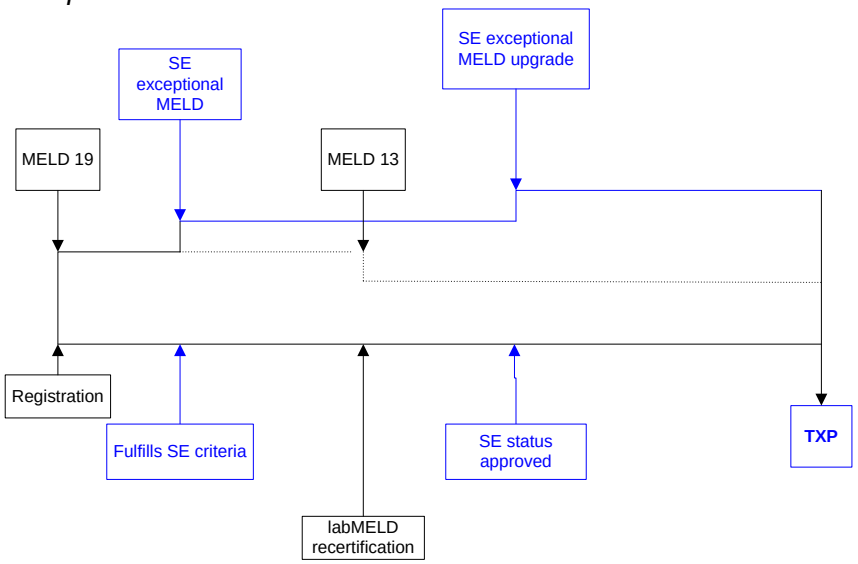
[55] NSE are only applied in Belgium, the Netherlands and Germany (as of December 3, 2007). Croatia started the NSE status as of May 17, 2016
[56] Release of March 16, 2021
[57] Netherlands: as of November 2, 2021

5.7.1.3 Recertification of lab MELD in SE/NSE patients

Any patient with an (N)SE exceptional MELD should have lab MELD recertified according to the recertification schedule.

5.7.1.3.1 Scheduled recertification while (non-)standard exception (SE)[58]

Example 1



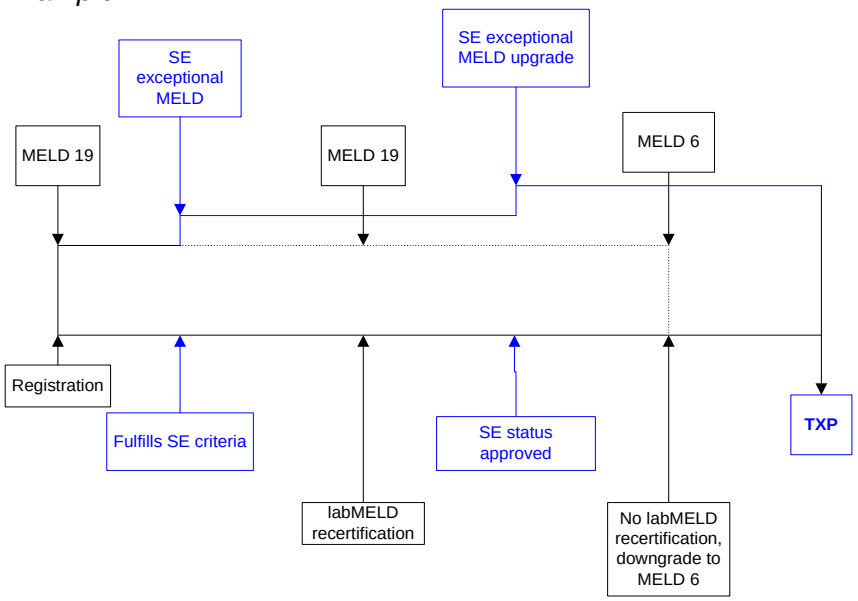
SE patient reached scheduled lab MELD recertification, lab MELD lower to previous and lower than SE exceptional MELD; SE exceptional MELD maintained.

After 90 days the patient's SE exceptional MELD is upgraded because the SE status is reconfirmed by the center; SE is valid for another 90 days.

Transplantation with upgraded SE exceptional MELD and recertified lab MELD.

[58] Same recertification rules apply for non-standard exceptions (NSE).

Example 2



SE patient reached scheduled lab MELD recertification, lab MELD identical to previous but lower than SE exceptional MELD; SE exceptional MELD maintained.

After 90 days the patient's SE exceptional MELD is upgraded because the SE status is reconfirmed by the center; SE is valid for another 90 days.

Upon next scheduled lab MELD recertification no data is entered, downgrade to MELD 6.

Transplantation with upgraded SE exceptional MELD and MELD 6.

Example 3

SE patient reached scheduled lab MELD recertification and is not recertified, i.e. downgraded to MELD 6 that is still lower than SE exceptional MELD; SE exceptional MELD maintained.

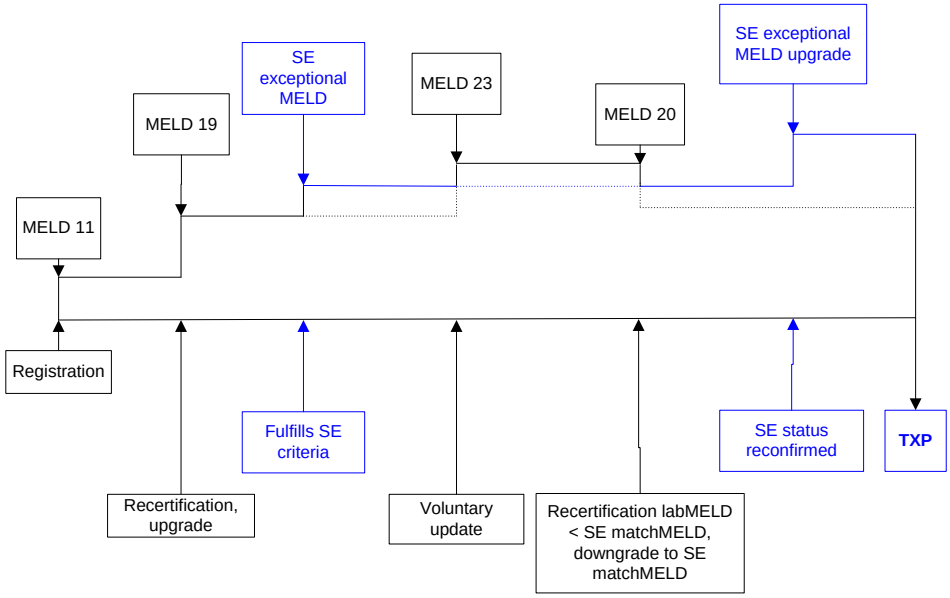
Transplantation with upgraded SE exceptional MELD and unrecertified MELD.

Example 4

SE patient upon scheduled lab MELD recertification not recertified and downgrade to MELD 6, which is lower than SE exceptional MELD; SE exceptional MELD maintained.

After 90 days the patient's SE status is not confirmed by the center and the patient is downgraded to the unrecertified lab MELD 6.

5.7.1.3.2 Voluntary update while standard exception (SE)



SE patient is voluntarily updated before he reaches scheduled recertification. Voluntarily updated lab MELD higher than SE exceptional MELD; voluntarily updated lab MELD applied.

Upon scheduled recertification of lab MELD data is entered and the lab MELD is now lower than the SE exceptional MELD; SE exceptional MELD applied.

After 90 days the patient's SE status is reconfirmed by the center and the SE exceptional MELD is upgraded; SE is valid for another 90 days.

Transplantation with upgraded SE exceptional MELD and recertified lab MELD.

5.7.1.4 Reconfirmation of exceptional MELD

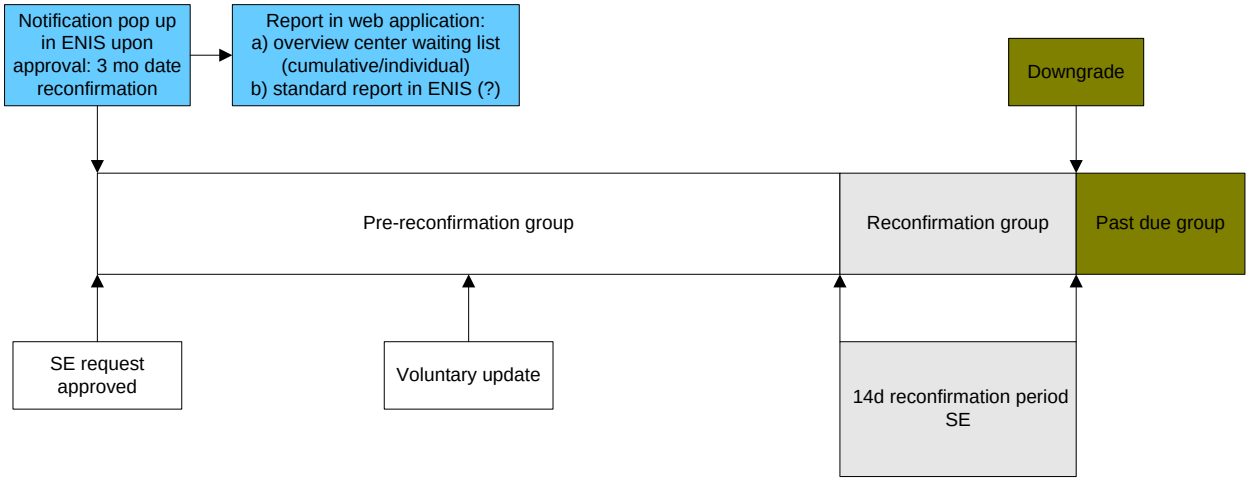
A patient's exceptional MELD has to be reconfirmed every 90 days. Both pediatric and adult patients must adhere to the reconfirmation schedule; exception and country-specific rules apply.

Transplant centers are responsible for the data entry of their patients' reconfirmation of an exceptional MELD.

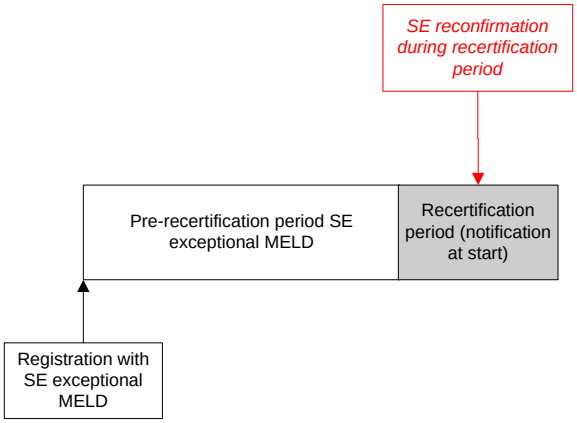
Any patient with an (N)SE exceptional MELD is eligible for an upgrade every 90 days; SE/NSE- and country-specific rules apply.

5.7.1.4.1 Reconfirmation of standard exception (SE)

Patients eligible for an SE, i.e. fulfill the SE criteria, must have their SE status reconfirmed by the center every 90 days.

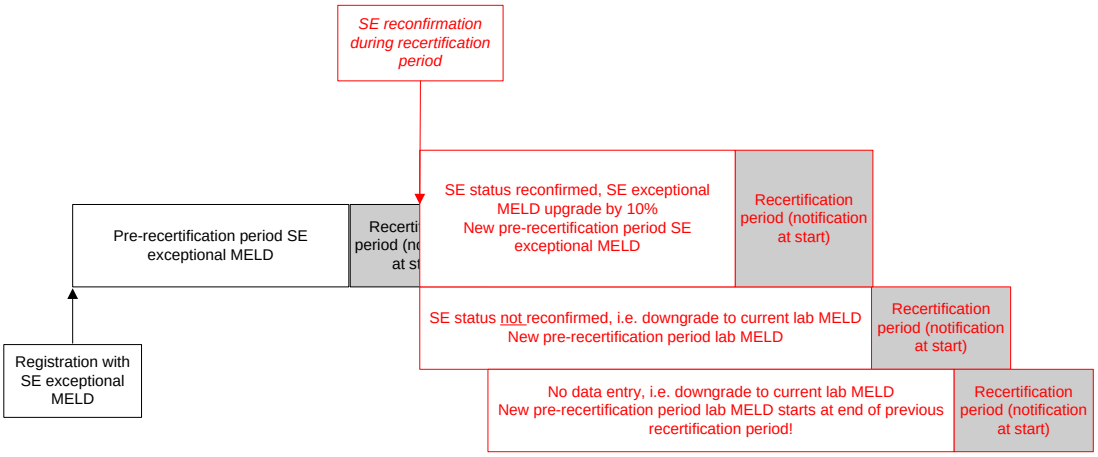


Patients with an SE exceptional MELD applied in the matching have to be reconfirmed at scheduled 90-day intervals. Centers can find information in the MELD-application.



If a patient's SE exceptional MELD is:

- reconfirmed, i.e. fulfills SE criteria, then the patient maintains the SE status and the SE exceptional MELD is upgraded and the new 90-day interval immediately starts; country and disease-specific rules apply;
- not reconfirmed, i.e. the patient does not fulfill the SE criteria, then the patient is downgraded to his current (un)recertified lab MELD.

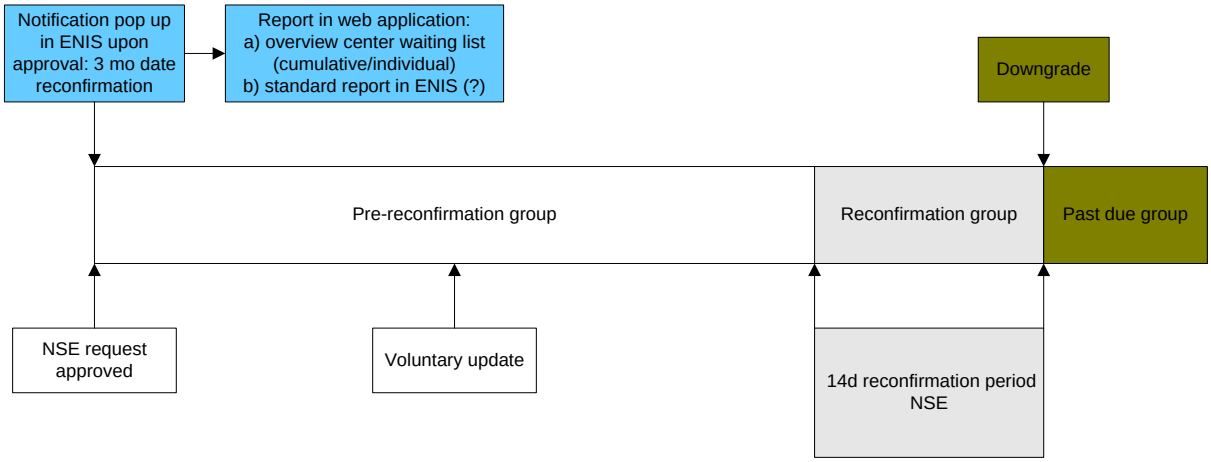


5.7.1.4.1.1 No data received at recertification date

If a patient's SE exceptional MELD is not recertified during the scheduled recertification period, then the patient is downgraded to the patient's current (un)recertified lab MELD at the end of the scheduled recertification period.

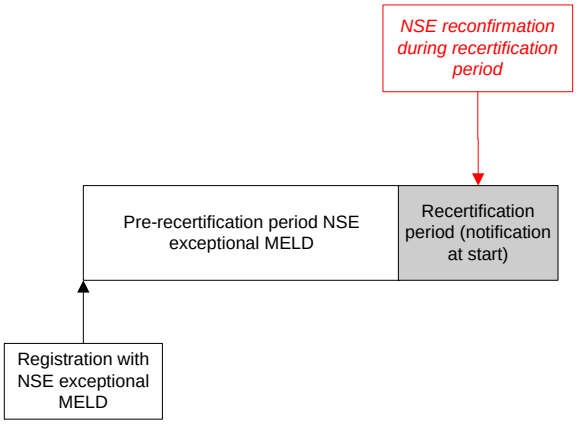
5.7.1.4.2 Reconfirmation of non-standard exception (NSE)

Every NSE patient's exceptional MELD (except for Belgium and the Netherlands[59]) must be recertified by presenting the patient again to the national audit group every 90 days.



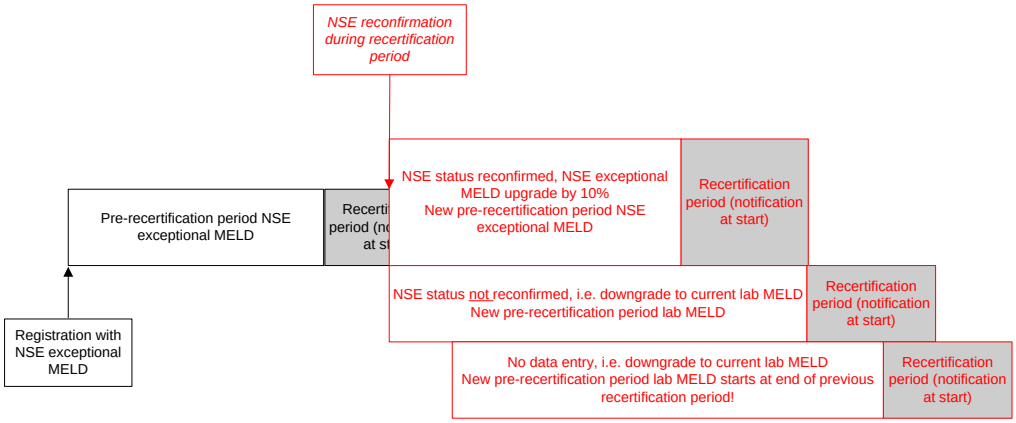
[59] Netherlands: as of November 2, 2021

Patients with an NSE exceptional MELD applied in the matching have to be reconfirmed at scheduled 90-day intervals. Centers can find information in the MELD-application.



If a patient's NSE exceptional MELD is:

- reconfirmed by the audit group, i.e. the patient is accepted for another NSE term, then the patient maintains his NSE status, the NSE exceptional MELD is upgraded by 10% 3-mo probability of death and the new 90-day interval immediately starts; country specific rules apply;
- not reconfirmed by the audit group, i.e. the patient is not accepted for another NSE term, then the patient is downgraded to his current (un)recertified lab MELD.



5.7.1.4.2.1 No data received at recertification date

If a patient's NSE exceptional MELD is not recertified during the scheduled recertification period, then the patient is downgraded to the patient's current (un)recertified lab MELD at the end of the scheduled recertification period.

5.8 Standard exception (SE), stratified by disease

A patient's urgency may not sufficiently be reflected by lab MELD. Some diseases have been identified and standardized and are called standard exceptions (SE). These diseases are comprised in a country-specific list.

To be eligible for SE, patients must fulfill disease- and country-specific criteria. Centers must fill in an online request form, either at initial registration or at any moment thereafter. If the request is complete and criteria are met, the patient is granted the initial SE exceptional MELD, expressed in percent [%] 3-month probability of death on the waiting list (see 5.12).

If the SE exceptional MELD, at time of matching, is:
- equal to or higher than lab MELD, then this exceptional MELD is applied.
- lower than the lab MELD, then the lab MELD is applied.

Eligible patients have their initial SE exceptional MELD granted for 90 days; deviant disease-specific rules apply. Before the end of the 90-day period, the SE status must be reconfirmed (see 5.7.1.4.1). An SE patient's lab MELD recertification schedule (see 5.7.1.3) does continue despite any valid SE exceptional MELD.

Explanation of symbols used:
✓ = active field in the MELD web application, i.e. must be marked
o = display only, cannot be marked in the MELD web application, i.e. contains additional information/guidelines

5.8.1 Biliary atresia[60]

Nº	Listing criteria	A	B/L	G	NL	SLO	CRO
1	Patient is <2 years old	✓	✓	✓	✓	✓	✓
2	Patient diagnosed with biliary atresia	✓	✓	✓	✓	✓	✓

The SE is applicable for patients with ENIS diagnose C02 Congenital biliary disease - Extrahepatic biliary atresia

5.8.1.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
60% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.1.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
15% MELD equivalent	✓	✓	✓	✓	✓	✓

Upon the 2nd birthday of the patient the SE MELD will be frozen. This frozen exceptional MELD is kept until transplantation.

[60] R-LAC 02.14, Implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015, for Germany as of May 16, 2017

5.8.2 Cholangiocarcinoma

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
1	Biliary strictures in cholangiogram and biopsy and/or cytology with proof of neoplasia (aneuploidy considered to be neoplasia)	✓		✓		✓	✓
2	Tumor unresectable due to technical considerations or underlying liver disease	✓		✓		✓	✓
3	Lesion (CT/MRI) <3cm in diameter	✓		✓		✓	✓
4	no intra- or extra hepatic metastases in CT/MRI (thorax, abdomen), no regional lymph nodes involved (exclusion via laparatomy)	✓		✓		✓	✓
5	Centre should operate according to ratified protocol	✓		✓		✓	✓

The SE is applicable for patients with ENIS diagnose E05 Cancers - Hepatic cholangiocellular carcinoma

5.8.2.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓		✓		✓	✓

5.8.2.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓		✓		✓	✓

5.8.3 Hepatic artery thrombosis

Austria, Croatia, Hungary and Slovenia:
Patients with a hepatic artery thrombosis for which the HU status is not applicable, are eligible for a SE Hepatic artery thrombosis.

The Netherlands, Belgium and Germany:
Patients with a hepatic artery thrombosis with severe clinical consequences for which the HU status is not applicable, are eligible for a SE Hepatic artery thrombosis.

Nº	Listing criteria	A	B/L	G	NL	SLO	CRO	HUN
1	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU*	✓	✓	✓	✓	✓	✓	✓

*For HU criteria please see Chapter 5.2.1

5.8.3.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO	HUN
50% MELD equivalent		✓		✓			
100% MELD equivalent	✓		✓		✓	✓	✓

For Germany: This SE will be audited as a NSE by the national audit group.

5.8.3.2 Upgraded SE exceptional MELD

No upgrade in this SE is possible. The re-evaluation of the applicability of the SE remains at every 90 days.

5.8.4 Hepatocellular carcinoma (HCC)

Eligible Patients: A patient with an HCC tumor that is stage T2 may be registered at a MELD score equivalent to a 15% probability of patient death within 3 months if the criteria listed in sections 2C-D are also met. For the purposes of this policy, stage T2 lesions are defined as

- 1 lesion >= 2 cm and <= 5cm; OR
- 2 or 3 lesions, >= 1cm and <= 3cm in size.

Nº	Listing criteria	A	B/L	G[61]	SLO	CRO
	Accepted ways of diagnosis of initial HCC (1 or more possible)	O	O		O	O
1a	Biopsy	✓	✓		✓	✓
1b	One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	✓	✓		✓	✓

Nº	exceptional MELD criteria	A	B/L	G	SLO	CRO
	Patient fulfills the Milan criteria at the time of request, one from 2a or 2b and both 3 and 4 have to be met	O	O		O	O
2a	Patient has 1 lesion >= 2 cm and <= 5cm	✓	✓		✓	✓
2b	Patient has 2 or 3 lesions, >= 1cm and <= 3cm in size	✓	✓		✓	✓
3	Patient has no extrahepatic metastases	✓	✓		✓	✓
4	Patient has no macrovascular invasion	✓	✓		✓	✓

Nº	Additional guidelines	A	B/L	G	SLO	CRO
	Patient does not fulfill the Milan criteria at the time of request, but was initially diagnosed with HCC (only 1 possible)	O	O		O	O
5a	inside the Milan criteria, and after treatment presenting with one lesion <2cm or no lesion at all at time of SE request, is still considered to be a transplant patient.	✓	✓		✓	✓
5b	inside the Milan criteria, and has lesion(s) exceeding the Milan criteria at time of SE request; must be submitted to the national audit group.		✓			
5c	outside the Milan criteria, and fulfilling the criteria only after downstaging at time of SE request.		✓			
5c	outside the Milan criteria, and fulfilling the criteria only after downstaging at time of SE request; must be submitted to the national audit group.					
5d	Outside Milan criteria, fulfilling up-to-seven criteria, PET negative		✓			
5e	Participating in German TOM Study[62]					

[61] For German criteria for the SE HCC see the Richtlinien at http://www.bundesaerztekammer.de

[62] NSE criteria for TOM study (70112651) implemented as tickbox in SE application on November 5, 2019. TOM study stopped per 28-02-21

Nº	Exclusion criterion	A	B/L	G	NL	SLO	CRO
	Patients with lesion(s) initially, and also after downstaging, outside the Milan criteria.	✓	✓		✓	✓	✓

The SE is applicable for patients with ENIS diagnoses *E01 Cancers - Hepatocellular carcinoma and cirrhosis*.
Patients with diagnosis *E02 Cancers - Hepatocellular carcinoma and non-cirrhotic liver* and *E03 Cancers - Hepatocellular carcinoma - Fibrolamellar* are no longer eligible for the SE HCC[63]. For these patients, a NSE can be requested. National guidelines as proposed by the HCC consensus meetings 2019 and 2020 can apply (See Auditor guidelines for NSE requests).

5.8.4.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent				✓		
15% MELD equivalent	✓	✓	✓		✓	✓

5.8.4.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.4.3 Pathology reports of explanted HCC livers

Centers must send the pathology report of the explanted liver to ET. The largest dimension of each tumor must be reported (i.e., 1.5cm x 2.5cm must be reported as 2.5cm). Nodules <1cm are considered to be indeterminate and are not used in assigning priority

Reports will be collected and analyzed by the ELIAC.

5.8.5 Hepatocellular carcinoma (HCC) the Netherlands[64]

Nº	Listing criteria	NL
	Accepted ways of diagnosis of initial HCC (1 or more possible)	O
1a	Biopsy	✓
1b	One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	✓

[63] Release of March 16, 2021. The Milan criteria, as used in the SE, originally are not intended for these patients as the criteria for HCC assume a cirrhotic liver and the number of cases is too small to justify new SE criteria
[64] New criteria implemented October 18, 2022. The mandatory 6 month wait time before applying for the SE is abolished.

Nº	exceptional MELD criteria	NL
	Patient fulfills criteria if maximum of two points (AFP model according to Duvoux et al)[65]	O
2a	Largest diameter, cm: <=3 (0 points)	
2b	Largest diameter, cm: 3-6 (1 points)	
2c	Largest diameter, cm: >6 (4 points)	
3a	Number of nodules: 1-3 (0 points)	
3b	Number of nodules: >=4 (2 points)	
4a	AFP level, ng/mL: <=100 (0 points)	
4b	AFP level, ng/mL: 100-1000 (2 points)	
4c	AFP level, ng/mL: >1000 (3 points)	

Nº	Additional guidelines	NL
	Additional optional criteria	O
5a	Inside the AFP criteria, and after treatment presenting with one lesion <=3cm or no lesion at all at time of SE request, is still considered to be a transplant patient.	✓
5b	Initially outside the AFP criteria and fulfilling the criteria only after downstaging	✓

The SE is applicable for patients with ENIS diagnoses *E01 Cancers - Hepatocellular carcinoma and cirrhosis*.
Patients with diagnosis *E02 Cancers - Hepatocellular carcinoma and non-cirrhotic liver* and *E03 Cancers - Hepatocellular carcinoma - Fibrolamellar* are no longer eligible for the SE HCC[66]. For these patients, a NSE can be requested. National guidelines as proposed by the HCC consensus meetings 2019 and 2020 can apply (See Auditor guidelines for NSE requests).

Upon wait list registration, the data field Date of Diagnosis is mandatory.

5.8.5.1 Initial SE exceptional MELD

Initial SE exceptional MELD	NL
10% MELD equivalent	✓

5.8.5.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	NL
10% MELD equivalent	✓

5.8.6 Non-metastatic hepatoblastoma

The SE for non-metastatic hepatoblastoma is no longer applicable as of May 16, 2017.
A request for HU status can be done directly via the HU request form.

[65] AFP model according to Duvoux et al; Liver Transplantation for Hepatocellular Carcinoma: A Model Including α-Fetoprotein Improves the Performance of Milan Criteria, Gastroenterology 2012; 143:986-994
[66] Release of March 16, 2021. The Milan criteria, as used in the SE, originally are not intended for these patients as the criteria for HCC assume a cirrhotic liver and the number of cases is too small to justify new SE criteria

5.8.7 Cystic fibrosis

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
1	Liver transplantation, FEV1 <40%	✓				✓	✓
2	Liver transplantation, FEV1 >40%		✓				
3	Liver transplantation with FEV1 >40%, otherwise combined liver-lung transplantation			✓			

5.8.7.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓		✓	✓

5.8.7.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓		✓	✓

5.8.8 Familial Amyloidotic Polyneuropathy (FAP)

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
1	Biopsy with proof of amyloid deposits in an organ	✓	✓	✓	✓	✓	✓
2	Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met))	✓	✓	✓	✓	✓	✓
3	Modified Polyneuropathy Disability (PND) Score <IIIb	✓	✓			✓	
4	Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length $[m]^2$)*S-Albumin [g/L]]	✓	✓			✓	

Nº	Additional guidelines	A	B/L	G	NL	SLO	CRO
	1 or more applicable			o			o
5	In case of liver transplantation without heart transplantation: no life-threatening rhythm disorders and/or cardiomyopathy with EF<40% ± NYHA II symptoms	o	o	✓	o	o	✓
6	In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated	o	o	✓	o	o	✓
7	Modified Polyneuropathy Disability (PND) Score <IIIb			✓	o		✓
8	Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length $[m]^2$)*S-Albumin [g/L]]			✓	o		✓
9	FAP liver should, whenever possible, be used for Domino liver transplantation	o	o	o	o	o	o

The SE is applicable for patients with ENIS diagnose F07 Metabolic diseases - Familial amyloidotic polyneuropathy

5.8.8.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent				✓		
15% MELD equivalent	✓	✓	✓		✓	✓

5.8.8.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.8.3 Modified Polyneuropathy Disability Score (PND)

A modified Polyneuropathy Disability (PND)[67] score is used to evaluate peripheral sensory and motor disturbances as follows:

Grade	Description
I	sensory disturbances in limbs without motor impairment
II	difficulty walking without the need of a walking aid
IIIa	one stick or one crutch required for walking
IIIb	two sticks or two crutches needed
IV	wheelchair required or patient confined to bed

5.8.8.4 Modified Body Mass Index (mBMI)

A modified Body Mass Index (mBMI) score is calculated as follows:
mBMI = (weight [kg] / length $[m]^2$) * S-Albumin [g/L]

5.8.9 Primary hyperoxaluria Type 1 (PH1)

Nº	Listing criteria	A	B/L	G	NL	SLO	CRO
1	AGT deficit proven in liver biopsy	✓	✓	✓	✓	✓	✓
2	or phenotypically proven and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[68]			✓			

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
	1 criterion applicable	O	O	O	O	O	O
3a	Preemptive liver transplantation, no renal injury	✓	✓	✓	✓	✓	✓
3b	Combined liver+kidney transplantation, no end-stage renal disease	✓	✓	✓	✓	✓	✓
3c	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal disease	✓	✓		✓	✓	
3c	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal insufficiency and renal replacement therapy.			✓			✓
3d	Patients <1 yr and combined liver+kidney transplantation	✓	✓		✓	✓	

The SE is applicable for patients with ENIS diagnose F08 Metabolic diseases - Primary hyperoxaluria

5.8.9.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO

[67] Sharma P, Perri RE, Sirven JE et al. Outcome of Liver Transplantation for Familial Amyloidotic Polyneuropathy. Liver Transplantation 2003; 12: 1273-1280.
[68] R-LAC 03.13, Implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands, Germany and Slovenia as of December 15, 2014, for Austria as of September 12, 2015.
Heterozygous mutation added for Germany on request of the BAK AG Leber, May 17, 2016. For other countries on September 24, 2019

3a = 10% MELD equivalent	✓	✓	✓	✓	✓	✓
3b = 10% MELD equivalent	✓	✓	✓	✓	✓	✓
3c = 15% MELD equivalent	✓	✓	✓		✓	✓
3c = 10% MELD equivalent				✓		
3d = MELD 40	✓	✓		✓	✓	

5.8.9.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
3a = 10% MELD equivalent	✓	✓	✓	✓	✓	✓
3b = 10% MELD equivalent	✓	✓	✓	✓	✓	✓
3c = 15% MELD equivalent	✓	✓	✓		✓	✓
3c = 10% MELD equivalent				✓		

If a pediatric patient reaches the age threshold as mentioned above, the exceptional MELD is frozen at the time the patient reaches the age threshold. This frozen exceptional MELD is kept until transplantation.

5.8.10 Polycystic liver disease (PLD)

Nº	**Listing criteria**	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
1	Massive PLD (total Cysts/Parenchyma >1) and complication(s), that can exclusively be treated by liver transplantation	✓	✓			✓	✓
2	clinically apparent liver disease due to massive PLD, incl. weight loss, ascites, portal hypertension	✓	✓			✓	✓
3	Failure of non-transplant related interventions or contraindications for further non-transplant related interventions	✓	✓			✓	✓
4	Contraindications for non-transplant related interventions, fulfilling criteria 1 and 2	✓	✓			✓	✓
5[69]	Patient has been listed actively on the liver waiting list for ≥365 days and				O		

[69] Counted as 365 consecutive days

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
	1 or more in combination with <u>all</u> listing criteria	O	O		O	O	O
	1 or more			O			
6a	Ascites or variceal bleeding <u>or</u>	✓	✓	✓		✓	✓
6b	Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography) <u>or</u>	✓	✓	✓	✓	✓	✓
6c	Ascites complicating cyst fenestration procedures <u>or</u>	✓	✓	✓	✓	✓	✓
6d	Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm <u>or</u>	✓	✓	✓	✓	✓	✓
6e.1	Dialysis dependency in combination with one criterion from a-d	O	O			O	O
6e.1	Dialysis dependency in combination with one criterion from a-d (combined liver-kidney transplantation to be evaluated)			O			
6e.2	Dialysis dependency in combination with one criterion from b-d				O		
6f.1	Creatinine-Clearance 20-30ml/min in combination with one criterion from a-e.1	O	O			O	O
6f.1	Creatinine-Clearance 20-30ml/min in combination with one criterion from a-e.1(combined liver-kidney transplantation to be evaluated)			O			
6f.2	Creatinine-Clearance 20-30ml/min in combination with one criterion from b-e.2				O		

The SE is applicable for patients with ENIS diagnose H05 Benign liver tumors or Polycystic disease

5.8.10.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.10.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.11 Urea-cycle disorder/organic acidemia

The SE for urea-cycle disorder/organic acidemia is no longer applicable as of September 24, 2019.
A request for HU status can be done directly via the HU request form.

5.8.12 Hepato-pulmonary syndrome (HPS)

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
1	Proof of liver disease	✓	✓	✓	✓	✓	✓
2	PaO2 <60 mmHg at rest (sitting/ supine ambient air)	✓	✓	✓	✓	✓	✓
3	Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography	✓	✓	✓	✓	✓	✓
4	No alternative pulmonary disease to explain hypoxemia	✓	✓	✓	✓	✓	✓

5.8.12.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent				✓		
15% MELD equivalent	✓	✓	✓		✓	✓

5.8.12.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.13 Porto-pulmonary hypertension (PoPH)

Nº	exceptional MELD criteria	A	B/L	G	NL	SLO	CRO
1	Proof of underlying liver disease	✓	✓	✓	✓	✓	✓
2	PAP: 25 < PAPm < 35 mmHg (with or without therapy)	✓	✓	✓	✓	✓	✓
3	Pulmonary vascular resistance (PVR) ≥240 dyn.s.cm^{-5}	✓	✓	✓	✓	✓	✓
4	Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg	✓	✓	✓	✓	✓	✓
5	All mentioned values have to be documented by right heart catheterization	✓	✓	✓	✓	✓	✓

5.8.13.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
25% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.13.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓	✓	✓	✓

5.8.14 Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation This SE replaces the current SE "small for size syndrome"

Nº	exceptional MELD criteria	A	B/L	G	NL[70]	SLO	CRO
	Criterion 1 must be met and 2 or more other criteria of the criteria 2 - 5	O	O	O		O	O
1	Less than 3 months after liver transplantation	✓	✓	✓		✓	✓
2	Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction and/or	✓	✓	✓		✓	✓
3a	Non-anastomotic bile duct strictures documented by MRI or ERCP	✓	✓			✓	✓
3b	Bile duct ischemia / ITBL (Non-anastomotic biliary strictures documented by MRI or ERCP) and/or			✓			
4	INR ≥ 1.5 and/or	✓	✓	✓		✓	✓
5	Ascites and/or	✓	✓	✓		✓	✓

[70] LOL conference September 12, 2008: this SE will be audited as a NSE (as of 22-04-2009).

5.8.14.1 Initial SE exceptional MELD

Initial SE exceptional MELD	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
Match MELD corresponding to a 3- months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus b) 20% 3-months mortality	✓	✓	✓		✓	✓

5.8.14.2 Upgraded SE exceptional MELD

Re-confirmation of the SE is needed after every 90 days, however no upgrade will take place. The SE MELD score will be changed whenever a new Lab MELD score is inserted into the system.

5.8.15 Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)

Nº	**exceptional MELD criteria**	**A**	**B/L**	**G**	**NL**[71]	**SLO**	**CRO**
	All listing criteria have to be met	O	O	O		O	O
1	Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis)	✓	✓	✓		✓	✓
2	High output congestive heart failure	✓	✓	✓		✓	✓
3	Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver transplantation	✓	✓	✓		✓	✓

5.8.15.1 Initial SE exceptional MELD

Initial SE exceptional MELD	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
15% MELD equivalent	✓	✓	✓		✓	✓

5.8.15.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
10% MELD equivalent	✓	✓	✓		✓	✓

5.8.15.3 Initial SE exceptional MELD in case of acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome)

Initial SE exceptional MELD	**A**	**B/L**	**G**	**NL**	**SLO**	**CRO**
MELD 40 (no HU status)	✓	✓	✓		✓	✓

[71] LOL conference September 12, 2008: this SE will be audited as a NSE (as of 20-09-2008).

5.8.16 Hepatic hemangioendothelioma

Nº	exceptional MELD criteria	A	B/L	G	NL[72]	SLO	CRO
	All listing criteria have to be met	O	O	O		O	O
1	Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens on endothelial cells.	✓	✓	✓		✓	✓
2	Patient has to be on the liver transplant waiting list for at least one year	✓	✓	✓		✓	✓

5.8.16.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	G	NL	SLO	CRO
15% MELD equivalent	✓	✓	✓		✓	✓

5.8.16.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	A	B/L	G	NL	SLO	CRO
10% MELD equivalent	✓	✓	✓		✓	✓

Pathology reports of explanted livers
Centers must send the pathology report of the explanted liver to ET. Reports will be collected and analyzed by the ELIAC.

5.8.17 Biliary sepsis

Nº	exceptional MELD criteria	A	B/L	NL[73]	SLO	CRO
	Biliary sepsis can only be treated by liver transplantation				O	O
	All listing criteria have to be met				O	O
1	At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions)				✓	✓
2	Septicemia in spite of antibiotic therapy (i.e. source of infection cannot be eliminated)				✓	✓

5.8.17.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	NL	SLO	CRO
Match MELD corresponding to a 3- months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus b) 20% 3-months mortality.			✓	✓	✓

5.8.17.2 Upgraded SE exceptional MELD

Re-confirmation of the SE is needed after every 90 days, however no upgrade will take place. The SE MELD score will be changed whenever a new Lab MELD score is inserted into the system.

[72] LOL conference September 12, 2008: this SE will be audited as a NSE (as of 20-09-2008). Initial exceptional MELD points will be calculated as the Initial SE exceptional MELD.
[73] LOL conference September 12, 2008: this SE will be audited as a NSE (as of 20-09-2008). Initial exceptional MELD points will be calculated as the Initial SE exceptional MELD.

5.8.18 Biliary sepsis/ Secondary sclerosing cholangitis (SSC) Germany

Nº	exceptional MELD criteria	G
	Biliary sepsis can only be treated by liver transplantation	O
	All listing criteria have to be met	O
1	At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions)	✓
2	Septicemia in spite of antibiotic therapy (i.e. source of infection cannot be eliminated)	✓

5.8.18.1 Initial SE exceptional MELD

Initial SE exceptional MELD	G
Match MELD corresponding to a 3- months mortality calculated as the sum of: c) 3-month mortality on the Lab MELD plus d) 30% 3-months mortality.	✓

5.8.18.2 Note

Included are complications due to liver transplantation such as ITBL, ischemia/ vascular thrombosis, Bile duct necrosis, diffuse Bile duct damage, vanishing bile duct syndrome.

5.8.18.3 Upgraded SE exceptional MELD

Re-confirmation of the SE is needed after every 90 days, however no upgrade will take place. The SE MELD score will be changed whenever a new Lab MELD score is inserted into the system.

5.8.19 Primary sclerosing cholangitis (PSC)

Nº	exceptional MELD criteria	A	B/L		NL[74]	SLO	CRO
	PSC has to be diagnosed according to standard radiology criteria					O	O
	At least two listing criteria have to be met					O	O
1	At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions)					✓	✓
2	Splenomegaly > 12 cm					✓	✓
3	Body Mass Index-Reduction > 10% within 12 months.					✓	✓

5.8.19.1 Initial SE exceptional MELD

Initial SE exceptional MELD	A	B/L	NL	SLO	CRO
Match MELD corresponding to a 3- months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus b) 20% 3-months mortality.			✓	✓	✓

[74] LOL conference September 12, 2008: this SE will be audited as a NSE (as of 20-09-2008). Initial exceptional MELD points will be calculated as the Initial SE exceptional MELD.

5.8.19.2 Upgraded SE exceptional MELD

Re-confirmation of the SE is needed after every 90 days, however no upgrade will take place. The SE MELD score will be changed whenever a new Lab MELD score is inserted into the system.

5.8.20 Primary sclerosing cholangitis (PSC) Germany

Nº	exceptional MELD criteria	G
	Listing criteria	
	MRCP or ERC proven and not interventionally resolvable stricture of the common bile duct (CBD) or main lobular bile ducts (RBD and LBD) with symptoms of an obstructive cholestasis and a total bilirubin of ≥ 6 mg/dl during 6 months. Secondary sclerosing cholangitis needs to be ruled out.	✓

In case of recipients ≤18 years, a NSE needs to be requested.

5.8.20.1 Initial SE exceptional MELD

Initial SE exceptional MELD	G
35% MELD equivalent	✓

5.8.20.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	G
10% MELD equivalent	✓

5.8.21 Neuroendocrine tumors (NET) Germany[75]

Nº	exceptional MELD criteria	G
	All listing criteria have to be met	O
1	Non-resectable[a] highly differentiated gastro-entero-pancreatic neuroendocrine tumor (GEP-NET) liver metastases[b] with porto-venous drainage[c] confined to the liver exclusively[d]	✓
2	Stable disease since >6 months after resection of the primary tumor and of possible extra-hepatic metastases before requesting SE.	✓
3	Obligatory audit and decision in the center's tumor board.	✓

Note:
-Non-resectable[a:] generally diagnosed by multiphase CT or liver specific CE MRT or other standard of care diagnostic procedure
-Highly differentiated gastro-entero-pancreatic neuroendocrine tumor (GEP-NET) liver metastases[b]: Ki-67/MiB status necessary
- with porto-venous drainage[c]: patients with NET metastases originating from the distal rectum, esophagus, lung, adrenal, and thyroid are excluded from SE
-confined to the liver exclusively[d]: exclusion of extra-hepatic metastases in solid organs (lung, bones) via PET or Somatostatin receptor scintigraphy or DOTA/DOTATOC

[75] Implemented June 20, 2017. More info can be found in the Richtlinien at http://www.bundesaerztekammer.de

scintigraphy, or methods according to the latest scientific guidelines defined by the transplant center's tumor board.

The SE is applicable for patients with ENIS diagnose E10 Cancers - Secondary liver tumors - Other neuroendocrine

5.8.21.1 Initial SE exceptional MELD

Initial SE exceptional MELD	**G**
15% MELD equivalent	✓

5.8.21.2 Upgraded SE exceptional MELD

Upgrade SE exceptional MELD	**G**
10% MELD equivalent	✓

Recertification must be done every 3 months according to above mentioned diagnostic methods approved by the tumor board of the center.

Appearance of extrahepatic progression, i.e. lymph node metastases leads to delisting but re-listing is possible after a 6 month interval of extrahepatic freedom of cancer.

Extrahepatic metastases in solid organs lead to permanent exclusion from transplantation.

5.9 Prospective audit for exceptional MELD

Some diseases have been identified as so-called standard exceptions (SE). Nonetheless, patients not eligible for an SE can be presented to a national audit group for prospective evaluation in case:

- SE criteria ask for an audit;
- the patient does not fulfill SE criteria;
- the patient has a disease not listed in the SE list, i.e. a non-standard exception (NSE).
- Specified national exceptions

In order to be eligible for an (N)SE status under the above-mentioned conditions, patients must be prospectively evaluated by a national audit. Centers must fill in an online form stating their motivation why this patient should receive an exceptional NSE status, either at the initial registration or at any moment thereafter. If eligibility is checked and granted, the patient receives an initial NSE exceptional MELD, expressed in percent [%] 3-month probability of death on the waiting list.

If the disease-specific exceptional MELD is equal to or higher than the lab MELD, then this exceptional MELD will be used in the matching. If the disease-specific exceptional MELD is lower than the lab MELD, then the lab MELD will be used in the matching.

Eligible patients have their initial NSE exceptional MELD granted for 90 days (except for Belgium and the Netherlands).
Before the end of the 90-day period, the NSE status must be reconfirmed by presenting the patient again to the national audit group (See Reconfirmation of non-standard exception (NSE)). An NSE patient's lab MELD recertification, either scheduled or voluntary (see Recertification of lab MELD in SE/NSE patients) does continue despite any NSE exceptional MELD applied.

5.9.1 Prospective audits for non-standard exception (NSE)

An ET country can establish a national audit. A national audit group has the task to prospectively evaluate initial and reconfirmation (N)SE requests. The result of the audit is reported back to ET. If the result is positive, then the patient is granted the (N)SE status in ENIS, allowing him to receive the country-specific initial (N)SE exceptional MELD.

The result of the audit is reported back to ET. If the result is positive, then the patient is granted an upgrade of his previous (initial) exceptional MELD in a defined step; country-specific rules apply.

A NSE status can be requested via the MELD-application on the member site.

5.9.1.1 Auditor guidelines for NSE requests

Since the SE HCC is no longer applicable[76] for patients with diagnosis *E02 Cancers - Hepatocellular carcinoma and non-cirrhotic liver* and *E03 Cancers - Hepatocellular carcinoma – Fibrolamellar*, a NSE criteria guideline has been formulated during the HCC consensus meetings of 2019 and 2020 and has been proposed to the national NSE audit groups for discussion. The criteria guideline is meant as a tool for the auditors, therefore auditors can deviate from this guideline.

[76] Release of March 16, 2021

Proposed NSE criteria guideline non-cirrhotic and fibrolamellar HCC[77]

NSE Fibrolamellar
HCC Biopsy confirmation mandatory, including tumor-adjacent or other extra tumoral liver tissue, excluding cirrhosis.
• Markers for Keratin 7 and CD68 +,
• Betacatenin mutation excluded (for DD betacatenin mutated adenoma)
• Glutamin synthetase expression excluded (for DD betacatenin mutated adenoma)
• Keratin 19 excluded (for DD Keratin 19 positive HCC)

NSE non-cirrhotic HCC
Biopsy confirmation mandatory including tumor-adjacent liver tissue or other extra tumoral liver tissue excluding cirrhosis.
• Markers: a fibrous tissue stain like Masson, reticulin or Sirius Red to exclude cirrhosis Markers for adenoma: glutamin sythetase and betacatenin stain for beta catenin positive adenoma.
• Not resectable (definition): as decided by the tumor board based on imaging, pathology, liver function and reported performance status and comorbidity: Reason: indication of irresectability and candidacy for liver transplantation can be difficult Inclusion for transplantation in a non-cirrhotic liver can include patients without (F0) or with F0-F2 fibrosis, including patients with positive HBV- or HCV serology, or e.g. NASH.
• Categories that are also included are clear cell HCC and beta catenin positive adenoma with HCC.

Exclusion
• extrahepatic disease,
• gross macroscopic invasion:
o invasion of the portal- or caval vein.
o (hilar) lymph node involvement; this can be depicted on scan E.g. a PET-CT; in eligible patients explorative laparotomy of station 8&9 lymph nodes should be performed, with exclusion for OLT in case of positivity
• Advanced fibrosis (metavir) staging F3/F4 in pathology (F3 is also regarded as cirrhosis here).
• intra-hepatic tumor recurrence <12 months after surgery.

These NSE criteria guidelines are not valid for children (lack of extensive literature).

5.9.1.2 Belgium

The corresponding (N)SE request must be completed in the MELD-application on the membersite by the requesting center on all items[78]. The patient then receives the pending status. The request will be forwarded to the Be-LIAC auditors from outside the requesting center automatically[79]. In a split decision, a third Be-LIAC member will decide on the approval or denial of the (N)SE request (this is also part of the automatic process). Upon approval of the audit the initial (N)SE exceptional MELD or an upgrade, respectively, is granted and applied accordingly in ENIS.

All results from (N)SE audits are sent to the Be-LIAC on a regular basis for further

[77] Fibrolamellar carcinoma: A histologically unique tumor with unique molecular findings. Graham RP, Torbenson MS. Semin Diagn Pathol. 2017 Mar;34(2):146-152. doi: 10.1053/j.semdp.2016.12.010. Epub 2016 Dec 23. PMID: 28110996
Hepatocellular adenomas: review of pathological and molecular features. Beaufrère A, Paradis V. Hum Pathol. 2020 Dec 9:S0046-8177(20)30242-2. doi: 10.1016/j.humpath.2020.11.016. Online ahead of print. PMID: 33307077

[78] Be-LIAC decision dated September 19, 2006.
[79] See Meld Audit manual on the Eurotransplant Membersite.

analysis.

A remote center cannot assign any (N)SE exceptional MELD. A NSE exceptional MELD is reconfirmed automatically. However, the transplant center should remove the patient from the (N)SE status if the clinical status of a patient improves or worsens beyond the (N)SE criteria.

5.9.1.3 The Netherlands

The corresponding (N)SE request must be completed in the MELD-application by the requesting center on all items[80]. The patient then receives the pending status. The request will be forwarded to the auditors from outside the requesting center automatically. The audit group comprises auditors from all Dutch liver transplant centers (Groningen (NGRTP), Leiden (NLBTP), Rotterdam (NRDTP)).

Upon approval of the audit the initial (N)SE exceptional MELD or an upgrade, respectively, is granted and applied accordingly in ENIS.

All results from NSE audits are sent to the Landelijk Overleg Levertransplantatie (LOL) on a regular basis for further analysis.

A remote center cannot assign any (N)SE exceptional MELD.
A NSE exceptional MELD is reconfirmed automatically. However, the transplant center should remove the patient from the (N)SE status if the clinical status of a patient improves or worsens beyond the (N)SE criteria.
SE's that are audited up each re-evaluation, are not reconfirmed automatically.

5.9.1.4 Germany

The corresponding (N)SE request must be completed in the MELD web application by the requesting center on all items. The patient then receives the pending status. The ET duty desk will then forward the request to two auditors[81] from outside the requesting center for evaluation. In a tie situation, a third auditor will decide on the approval or denial of the (N)SE request. Upon approval of the audit the initial (N)SE exceptional MELD or an upgrade, respectively, is granted and applied accordingly in ENIS.

All results from (N)SE audits are sent to the German auditors on a regular basis for further analysis.

A remote center cannot assign any (N)SE exceptional MELD. However, the transplant center should remove the patient from the (N)SE status if the clinical status of a patient improves or worsens beyond the (N)SE criteria.

5.9.1.5 Croatia[82]

[81] The Audit group comprises auditors from several centers.
[82] Since May 17, 2016

The corresponding (N)SE request must be completed in the MELD-application by the requesting center on all items. The patient then receives the pending status. The request will be forwarded to the auditors from outside the requesting center automatically. The audit group comprises auditors from all Croatian liver transplant centers (Zagreb University (CZATP) and Zagreb Merkur (ZCMT)).

Upon approval of the audit the initial (N)SE exceptional MELD or an upgrade, respectively, is granted and applied accordingly in ENIS.

5.9.1.6 Specified national NSE exceptions

Each country can decide on exceptional NSE cases with increased initial NSE scores, for instance for studies. These specific studies can be initiated via the MELD application. After approval of the NSE, the MELD application will directly grant the corresponding NSE points. The 90 day increase in MELD score will be done automatically, according to the standard procedure.

Country	Exceptional case or study	Approval	Initial NSE score
Netherlands	CCA *	Via study PI, 1 NSE auditor	38
Netherlands	CRM *	1 NSE auditor	28
Netherlands	Other oncological indications: * - NET - HCC non-cirrhotic liver	1 NSE auditor	20
Belgium	Terlipressine treatment for HRS	NSE audit	30
Germany	PRO-DUCT 002	Via study PI	38

* A backup offer will be made in the initially accepting center in the Netherlands.[83]

5.9.2 Prospective audits for standard exception (SE)

An SE may require an audit by the national audit group[84]. The center must first access the MELD web application to request the SE and the patient is assigned the pending status. The center then sends the SE request to the national audit group. After receiving a vote from all auditors, the requesting transplant center sends the SE request completed on all items with a confirmation concerning its approval or denial, respectively, to the ET duty desk.

In case of a reconfirmation of an SE patient the transplant center, that was sent a notification for a reconfirmation, must first access the MELD web application and press the reconfirm button for this patient. The patient then receives the pending status.

[83] Requested by LOL Netherlands, December 2024
[84] Currently this concerns only HCC cases in Belgium and the Netherlands; country and disease-specific SE rules apply.

Upon approval of the audit the initial SE exceptional MELD or an upgrade, respectively, is granted and applied accordingly in ENIS.

All results from SE audits are sent to national authorities on a regular basis for further analyses.

A remote center cannot assign an SE exceptional MELD. However, the transplant center should remove the patient from the SE status if the clinical status of a patient improves or worsens beyond the SE criteria.

5.9.3 Deviant national regulations

Countries can decide whether to adopt the NSE procedure or not. The following countries have no NSE procedure, i.e. a national audit group:

- Austria
- Hungary
- Slovenia

NSE can therefore not be requested in these countries.

5.10 Addendum A - standard exception lists

5.10.1 Austria[85]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	*Exceptional MELD criteria:* 1. Patient is <2 years old 2. Patient diagnosed with biliary atresia	60%	+15%
Cholangiocarcinoma	*Exceptional MELD criteria:* 1. Biliary strictures in cholangiogram and biopsy and/or cytology with proof of neoplasia (aneuploidy considered to be neoplasia); 2. Tumor unresectable due to technical considerations or underlying liver disease; 3. Lesion (CT/MRI) <3cm in diameter; 4. no intra- or extrahepatic metastases in CT/MRI (thorax, abdomen), no regional lymph nodes involved (exclusion via laparatomy); 5. Centre should operate according to ratified protocol.	10%	+10%
Cystic fibrosis	*Exceptional MELD criteria:* Liver transplantation, FEV1 <40%	10%	+ 10%
Familial Amyloidotic Polyneuropathy (FAP)	*Exceptional MELD-criteria:* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)). 3. Modified Polyneuropathy Disability (PND) Score <IIIb; 4. Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length $[m]^2$)*S-Albumin [g/L]];	15%	+ 10%
	Additional guidelines: 1. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF<40% ± NYHA II symptoms; 2. In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated; 3. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*Exceptional MELD-criteria:* 1. Proof of liver disease; 2 PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	15%	+10%
Porto-pulmonary hypertension (PoPH)	*exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy); 3. Pulmonary vascular resistance (PVR) ≥240 $dyn.s.cm^{-5}$; 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization.	25%	+ 10%
Primary Hyperoxaluria Type 1 (PH1)	*Listing criterion:* AGT deficit proven in liver biopsy or phenotypically and confirmed by genetic analysis showing a homozygous		

[85] List approved by Austrian ELIAC representative (R. Steininger).

(Oxalosis)	or heterozygous mutation for primary hyperoxaluria type 1[86]		
	Exceptional MELD-criteria (1 criterion applicable):		
	Preemptive liver transplantation, no renal injury.	10%	+ 10%
	Combined liver+kidney transplantation, no end-stage renal disease.	10%	+ 10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal disease.	15%	+ 10%
	Patients <1 yr and combined liver+kidney transplantation.	MELD 40	

Polycystic liver disease (PLD)	*Listing criteria:* 1. Massive PLD (total Cysts/Parenchyma >1) and complication(s), that can exclusively be treated by liver transplantation; 2. clinically apparent liver disease due to massive PLD, incl. weight loss, ascites, portal hypertension; 3. Failure of non-transplant related interventions or contraindications for further non-transplant related interventions; 4. Contraindications for non-transplant related interventions, fulfilling criteria 1 and 2.		
	Exceptional MELD criteria (1 or more in combination with <u>all</u> listing criteria): 1. Ascites or variceal bleeding; 2. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 3. Ascites complicating cyst fenestration procedures; 4. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 5. Dialysis dependency in combination with one criterion (1-4); 6. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-5).	10%	+10%
Hepatocellular Carcinoma (HCC)	*Exceptional MELD criteria:* Patient has 1 lesion ≥ 2 cm and ≤ 5cm or 2 or 3 lesions ≥ 1cm and ≤ 3cm in size, no extrahepatic metastases and no macrovascular invasion (Milan criteria). Accepted ways of diagnosis of HCC (at least 1): 1. Biopsy, *or* 2. One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	15%	+ 10%
	Additional guidelines: 1. Patients must fulfill the Milan criteria at the time of upgrade in 3-monthly steps. 2. Patients initially: - inside the Milan criteria and, after treatment with one lesion <2cm or no lesion at all at time of request, are still considered to be transplant patients. - inside the Milan criteria and lesion(s) exceeding the Milan criteria at time of request, are to be submitted to the national audit group. - outside the Milan criteria and fulfilling the criteria only after downstaging at time of request, are to be submitted to the national audit group.		
	Exclusion criterion:		

[86] R-LAC 03.13 regarding genetic analysis implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015

	Patients with lesion(s) initially, and also after downstaging, outside the Milan criteria.		

Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	100%	
Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation. This SE replaces the current SE "small for size syndrome".	*Exceptional MELD criteria (≥3 criteria):* 1 Less than 3 months after liver transplantation.; 2. Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction; 3 Non-anastomotic bile duct strictures documented by MRI or ERCP.; 4. INR ≥ 1.5; 5. Ascites;	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis) 2. High output congestive heart failure; 3. Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver transplantation 4. Acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome)	15% Meld 40	+10% Meld 40
Hepatic hemangioendothelioma	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens on endothelial cells.	15%	+10%
	Additional guidelines: 1. Patient has to be on the liver transplant waiting list for at least one year.		

5.10.2 Slovenia[87]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	*Exceptional MELD criteria:* 1. Patient is <2 years old 2. Patient diagnosed with biliary atresia	60%	+15%
Cholangiocarcinoma	*Exceptional MELD criteria:* 1. Biliary strictures in cholangiogram and biopsy and/or cytology with proof of neoplasia (aneuploidy considered to be neoplasia); 2. Tumor unresectable due to technical considerations or underlying liver disease; 3. Lesion (CT/MRI) <3cm in diameter; 4. no intra- or extrahepatic metastases in CT/MRI (thorax, abdomen), no regional lymph nodes involved (exclusion via laparatomy); 5. Centre should operate according to ratified protocol.	10%	+10%
Cystic fibrosis	*Exceptional MELD criteria:* Liver transplantation, FEV1 <40%	10%	+ 10%
Familial Amyloidotic Polyneuropathy (FAP)	*Exceptional MELD-criteria:* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)). 3. Modified Polyneuropathy Disability (PND) Score <IIIb; 4. Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length [m]2)*S-Albumin [g/L]];	15%	+ 10%
	Additional guidelines: 1. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF<40% ± NYHA II symptoms; 2. In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated; 3. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*exceptional MELD-criteria:* 1. Proof of liver disease; 2; PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	15%	+10%
Porto-pulmonary hypertension (PoPH)	*Exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy);; 3. Pulmonary vascular resistance (PVR) ≥240 dyn.s.cm^{-5} 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization.	25%	+ 10%
Primary Hyperoxaluria Type 1 (PH1) (Oxalosis)	*Listing criterion:* AGT deficit proven in liver biopsy or phenotypically and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[88].		
	exceptional MELD-criteria (1 criterion applicable):		

[87] List approved by Slovenian ELIAC representative (S. Markovicz, Sojar).
[88] R-LAC 03.13 regarding genetic analysis implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015

	Preemptive liver transplantation, no renal injury.	10%	+ 10%
	Combined liver+kidney transplantation, no end-stage renal disease.	10%	+ 10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal disease.	15%	+ 10%
	Patients <1 yr and combined liver+kidney transplantation.	MELD 40	
Polycystic liver disease (PLD)	*Listing criteria:* 1. Massive PLD (total Cysts/Parenchyma >1) and complication(s), that can exclusively be treated by liver transplantation; 2. clinically apparent liver disease due to massive PLD, incl. weight loss, ascites, portal hypertension; 3. Failure of non-transplant related interventions or contraindications for further non-transplant related interventions; 4. Contraindications for non-transplant related interventions, fulfilling criteria 1 and 2.		
	Exceptional MELD criteria (1 or more in combination with all listing criteria): 1. Ascites or variceal bleeding; 2. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 3. Ascites complicating cyst fenestration procedures; 4. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 5. Dialysis dependency in combination with one criterion (1-4); 6. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-5).	10%	+10%
Hepatocellular Carcinoma (HCC)	*Exceptional MELD criteria:* Patient has 1 lesion ≥ 2 cm and ≤ 5cm or 2 or 3 lesions ≥ 1cm and ≤ 3cm in size, no extrahepatic metastases and no macrovascular invasion (Milan criteria). Accepted ways of diagnosis of HCC (at least 1): 1. Biopsy, or 2. One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	15%	+ 10%
	Additional guidelines: 1. Patients must fulfill the Milan criteria at the time of upgrade in 3-monthly steps. 2. Patients initially: - inside the Milan criteria and, after treatment with one lesion <2cm or no lesion at all at time of request, are still considered to be transplant patients. - inside the Milan criteria and lesion(s) exceeding the Milan criteria at time of request, are to be submitted to the national audit group. - outside the Milan criteria and fulfilling the criteria only after downstaging at time of request, are to be submitted to the national audit group.		
	Exclusion criterion: Patients with lesion(s) initially, and also after downstaging, outside the Milan criteria.		

Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	100%	
Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation. This SE replaces the current SE" small for size syndrome".	*Exceptional MELD criteria (≥3 criteria):* 1 Less than 3 months after liver transplantation.; 2. Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction; 3 Non-anastomotic bile duct strictures documented by MRI or ERCP.; 4. INR ≥ 1.5; 5. Ascites;	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis) 2. High output congestive heart failure; 3. Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver transplantation 4. Acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome)	15% Meld 40	+10% Meld 40
Hepatic hemangioendothelioma	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens on endothelial cells.	15%	+10%
	Additional guidelines: 1. Patient has to be on the liver transplant waiting list for at least one year.		
Biliary sepsis	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions) 2. Septicemia in spite of antibiotic therapy (i.e. source of infection cannot be eliminated)	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
	Additional guidelines: 1. Biliary sepsis can only be treated by liver transplantation		
Primary sclerosing cholangitis (PSC)	*Exceptional MELD criteria (*At least two criteria have to be met *):* 1. At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions) 2. Splenomegaly > 12 cm; 3. Body Mass Index-Reduction > 10% within 12 months.	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	

	Additional guidelines: 1. PSC has to be diagnosed according to standard radiology criteria		

5.10.3 The Netherlands[89]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	*Exceptional MELD criteria:* 1. Patient is <2 years old 2. Patient diagnosed with biliary atresia	60%	+15%
Familial Amyloidotic Polyneuropathy (FAP)	*Exceptional MELD criteria:* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)).	10%	+10%
	Additional guidelines: 1. Modified Polyneuropathy Disability (PND) Score <IIIb; 2. Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length $[m]^2$)*S-Albumin [g/L]]; 3. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF <40% ± NYHA II symptoms; 4. In case of cardiac involvement and left ventricular wall thickness >12 mm combined lung-liver transplantation should be evaluated; 5. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*Exceptional MELD-criteria:* 1. Proof of liver disease; 2 PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	10%	+10%
Porto-pulmonary hypertension (PoPH)	*Exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy); 3. Pulmonary vascular resistance (PVR) ≥240 $dyn.s.cm^{-5}$; 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization	25%	+10%
Primary Hyperoxaluria Type 1 (PH1) (Oxalosis)	*Listing criteria:* AGT deficit proven in liver biopsy or phenotypically and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[90]		
	exceptional MELD criteria (1 criterion applicable):		

[89] List approved by the Landelijk Overleg Levertransplantatie (LOL).
[90] R-LAC 03.13 regarding genetic analysis implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015

	Preemptive liver transplantation, no renal injury.	10%	+10%
	Combined liver+kidney transplantation, no end-stage renal disease.	10%	+10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal disease.	10%	+10%
	Patients <1 yr and combined liver+kidney transplantation.	MELD 40	
Polycystic liver disease (PLD)	*Exceptional MELD criteria*: Patient has been listed actively on the liver waiting list for ≥365d and fulfills one or more of the following: 1. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 2. Ascites complicating cyst fenestration procedures; 3. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 4. Dialysis dependency in combination with one criterion (1-3); 5. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-4).	10%	+10%
Hepatocellular Carcinoma (HCC)[91]	*Exceptional MELD criteria:* Accepted ways of diagnosis of HCC (at least 1): 1. Biopsy, *or* 2. One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	10%	+ 10%
	Patient fulfills criteria if maximum of two points (AFP model according to Duvoux et al) 2a Largest diameter, cm: <=3 (0 points) 2b Largest diameter, cm: 3-6 (1 points) 2c Largest diameter, cm: >6 (4 points) 3a Number of nodules: 1-3 (0 points) 3b Number of nodules: >=4 (2 points) 4a AFP level, ng/mL: <=100 (0 points) 4b AFP level, ng/mL: 100-1000 (2 points) 4c AFP level, ng/mL: >1000 (3 points)		
	Additional optional criteria: 5a Inside the AFP criteria, and after treatment presenting with one lesion <=3cm or no lesion at all at time of SE request, is still considered to be a transplant patient. 5b Initially outside the AFP criteria and fulfilling the criteria only after downstaging		
Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	50%	

5.10.4 Germany[92]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	*Exceptional MELD criteria:* 1. Patient is <2 years old	60%	+15%

[91] As of October 18, 2022
[92] Richtlinien zur Organtransplantation gemäß §16 TPG, accessed via www.baek.de on December 4, 2006.

	2. Patient diagnosed with biliary atresia		
Hepatocellular carcinoma (HCC)	*Exceptional MELD criteria:* For German criteria for the SE HCC see the Richtlinien at http://www.bundesaerztekammer.de	15%	+ 10%
Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Polycystic liver disease (PLD)	*Exceptional MELD criteria (1 or more)*: 1. Ascites or variceal bleeding; 2. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 3. Ascites complicating cyst fenestration procedures; 4. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 5. Dialysis dependency in combination with one criterion (1-4) (combined liver-kidney transplantation to be evaluated); 6. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-5) (combined liver-kidney transplantation to be evaluated).	10%	+ 10%
Primary Hyperoxaluria Type 1 (PH1)	*Exceptional MELD criteria:* AGT deficit proven in liver or phenotypically and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[93]		
	Registration for pre-emptive liver transplantation, no significant renal injury.	10%	+ 10%
	Registration for combined liver+kidney transplantation, no end-stage renal insufficiency.	10%	+ 10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal insufficiency and renal replacement therapy.	15%	+ 10%
Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation. This SE replaces the current SE "small for size syndrome".	*Exceptional MELD criteria (≥3 criteria):* 1. Less than 3 months after liver transplantation; 2. Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction; 3 Bile duct ischemia / ITBL (Non-anastomotic biliary strictures documented by MRI or ERCP) and/or. ; 4. INR ≥ 1.5; 5. Ascites;	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
Cystic fibrosis	*Exceptional MELD criteria:* Liver transplantation with FEV1 >40%, otherwise combined liver-lung transplantation	10%	+ 10%
Familial Amyloidotic Polyneuropathy (FAP)	*Exceptional MELD-criteria (1 and 2 in combination with 1 or more criteria from 3-6):* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)).	15%	+ 10%
	Additional:		

[93] Heterozygous mutation added on request of the BAK AG Leber, May 17, 2016

	3. Neurologic symptoms or modified Polyneuropathy Disability (PND) Score <IIIb; 4. Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length [m]^2)*S-Albumin [g/L]]; 5. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF<40% ± NYHA II symptoms; 6. In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated; 7. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*Exceptional MELD-criteria:* 1. Proof of liver disease; 2; PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	15%	+10%
Porto-pulmonary hypertension (PoPH)	*Exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy);; 3. Pulmonary vascular resistance (PVR) ≥240 dyn.s.cm^{-5} 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization.	25%	+ 10%

Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Cholangiocarcinoma	*Exceptional MELD criteria:* 1. Biliary strictures in cholangiogram and biopsy and/or cytology with proof of neoplasia (aneuploidy considered to be neoplasia); 2. Tumor unresectable due to technical considerations or underlying liver disease; 3. Lesion (CT/MRI) <3cm in diameter; 4. no intra- or extrahepatic metastases in CT/MRI (thorax, abdomen), no regional lymph nodes involved (exclusion via laparatomy); 5. Centre should operate according to ratified protocol.	10%	+ 10%
Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis) 2. High output congestive heart failure; 3. Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver transplantation	15%	+10%

	4. Acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome)	40 Meld	40 Meld
Hepatic hemangioendothelioma	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens on endothelial cells.	15%	+10%
	Additional guidelines: 1. Patient has to be on the liver transplant waiting list for at least one year.		
Biliary sepsis/ Secondary sclerosing cholangitis (SSC) [94]	*Exceptional MELD criteria (*All listing criteria have to be met *):* 1. At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions) 2. Septicemia in spite of antibiotic therapy (i.e. source of infection cannot be eliminated)	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 30% 3-months mortality	
	Additional guidelines: 1. Biliary sepsis can only be treated by liver transplantation 2. Included are complications due to liver transplantation such as ITBL, ischemia/ vascular thrombosis, Bile duct necrosis, diffuse Bile duct damage, vanishing bile duct syndrome.		
Primary sclerosing[95] cholangitis (PSC)	*Exceptional MELD criteria* MRCP or ERC proven and not interventionally resolvable stricture of the common bile duct (CBD) or main lobular bile ducts (RBD and LBD) with symptoms of an obstructive cholestasis and a total bilirubin of ≥ 6 mg/dl during 6 months. Secondary sclerosing cholangitis needs to be ruled out. In case of recipients ≤18 years, a NSE needs to be requested.	35%	+ 10%
Neuroendocrine tumor (NET)[96]	*Exceptional MELD criteria* 1. Non-resectable (generally diagnosed by multiphase CT or liver specific CE MRT or other standard of care diagnostic procedure), highly differentiated gastro-entero-pancreatic neuroendocrine tumor (GEP-NET)	15%	10%

[94] Richtlinien zur Organtransplantation gemäß §16 TPG, der Tagesordnung der 05. Sitzung der Ständigen Kommission Organtransplantation am 22.11.2011 accessed via www.baek.de on December 4, 2006

[95] Richtlinien zur Organtransplantation gemäß §16 TPG, der Tagesordnung der 05. Sitzung der Ständigen Kommission Organtransplantation am 22.11.2011 accessed via http://www.baek.de/6

[96] More information can be found in the Richtlinien at http://www.bundesaerztekammer.de

	liver metastases (Ki-67/MiB status necessary) with porto-venous drainage (patients with NET metastases originating from the distal rectum, esophagus, lung, adrenal, and thyroid are excluded from SE) confined to the liver exclusively (exclusion of extra-hepatic metastases in solid organs (lung, bones) via PET or Somatostatin receptor scintigraphy or DOTA/DOTATOC scintigraphy, or methods according to the latest scientific guidelines defined by the center's tumor board). 2. Stable disease since >6 months after resection of the primary tumor and of possible extra-hepatic metastases before requesting SE. 3. Obligatory audit and decision in the center's tumor board		
	Additional guidelines: 1. Recertification must be done every 3 months according to above mentioned diagnostic methods approved by the tumor board of the center. 2. Appearance of extrahepatic progression, i.e. lymph node metastases leads to delisting but re-listing is possible after a 6 month interval of extrahepatic freedom of cancer. 3. Extrahepatic metastases in solid organs lead to permanent exclusion from transplantation.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	100%	

5.10.5 Belgium/Luxembourg[97]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	1. Patient is <2 years old 2. Patient diagnosed with biliary atresia	60%	+15%
Cystic fibrosis	Liver transplantation, FEV1 >40%	10%	+ 10%
Familial Amyloidotic Polyneuropathy (FAP)	*exceptional MELD-criteria:* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)). 3. Modified Polyneuropathy Disability (PND) Score <IIIb; 4. Modified BMI (mBMI) >700 [mBMI=(weight [kg]/length $[m]^2$)*S-Albumin [g/L]];	15%	+ 10%
	Additional guidelines:		

[97] List approved by Belgian Liver Intestine Committee (Be-LIAC).

	1. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF <40% ± NYHA II symptoms; 2. In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated; 3. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*exceptional MELD-criteria:* 1. Proof of liver disease; 2; PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	15%	+10%
Porto-pulmonary hypertension (PoPH)	*exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy);; 3. Pulmonary vascular resistance (PVR) ≥240 dyn.s.cm^{-5} 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization.	25%	+ 10%
Primary Hyperoxaluria Type 1 (PH1) (Oxalosis)	*Listing criteria:* AGT deficit proven in liver biopsy or phenotypically and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[98]		
	exceptional MELD-criteria (1 criterion applicable):		
	Preemptive liver transplantation, no renal injury.	10%	+ 10%
	Combined liver+kidney transplantation, no end-stage renal disease.	10%	+ 10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal disease.	15%	+ 10%
	Patients <1 yr and combined liver+kidney transplantation.	MELD 40	

Polycystic liver disease (PLD)	*Listing criteria:* 1. Massive PLD (total Cysts/Parenchyma >1) and complication(s), that can exclusively be treated by liver transplantation; 2. clinically apparent liver disease due to massive PLD, incl. weight loss, ascites, portal hypertension; 3. Failure of non-transplant related interventions or contraindications for further non-transplant related interventions; 4. Contraindications for non-transplant related interventions, fulfilling criteria 1 and 2.		
	exceptional MELD criteria (≥1 in	10%	+10%

[98] R-LAC 03.13 regarding genetic analysis implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015

	combination with listing criteria): 1. Ascites or variceal bleeding; 2. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 3. Ascites complicating cyst fenestration procedures; 4. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 5. Dialysis dependency in combination with one criterion (1-4); 6. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-5).		
Hepatocellular Carcinoma (HCC)	*exceptional MELD criteria:* Patient has 1 lesion ≥ 2 cm and ≤ 5cm or 2 or 3 lesions ≥ 1cm and ≤ 3cm in size, no extrahepatic metastases and no macrovascular invasion (Milan criteria). Accepted ways of diagnosis of HCC (at least 1): 1. Biopsy, *or* 2. One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	15%	+ 10%
	Additional guidelines: 1. Patients must fulfill the Milan criteria at the time of upgrade in 3-monthly steps. 2. Patients initially: - inside the Milan criteria and, after treatment with one lesion <2cm or no lesion at all at time of request, are still considered to be transplant patients. - inside the Milan criteria and lesion(s) exceeding the Milan criteria at time of request, are to be submitted to the national audit group. - outside the Milan criteria and fulfilling the criteria only after downstaging at time of request, are to be submitted to the national audit group.		
	Exclusion criterion: Patients with lesion(s) initially, and also after downstaging, outside the Milan criteria.		

Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	50%	
Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation. This SE replaces the current SE "small for size syndrome".	*exceptional MELD criteria (≥3 criteria):* 1 Less than 3 months after liver transplantation.; 2. Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction; 3 Non-anastomotic bile duct strictures documented by MRI or ERCP.; 4. INR ≥ 1.5; 5. Ascites;	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	

Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)	*exceptional MELD criteria (*All listing criteria have to be met *):* 1. Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis) 2. High output congestive heart failure; 3. Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver transplantation 4. Acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome)	15% Meld 40	+10% Meld 40
Hepatic hemangioendothelioma	*exceptional MELD criteria (*All listing criteria have to be met *):* 1. Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens on endothelial cells.	15%	+10%
	Additional guidelines: 1. Patient has to be on the liver transplant waiting list for at least one year.		

5.10.6 Croatia[99]

Disease	Criteria	Initial exceptional MELD	Upgrade in 90-day steps
Biliary atresia	1. Patient is <2 years old 2. Patient diagnosed with biliary atresia	60%	+15%
Hepatocellular carcinoma (HCC)	*exceptional MELD criteria:* Patient has 1 lesion ≥ 2 cm and ≤ 5cm or 2 or 3 lesions ≥ 1cm and ≤ 3cm in size, no extrahepatic metastases and no macrovascular invasion (according to Milan criteria). Accepted ways of diagnosis of HCC: 1. Biopsy, *or* 2. One positive result with hypervascularization in arterial phase and wash out in portal phase, with imaging technique (multiphase contrast enhanced CT, multiphase contrast enhanced MRI or gadoxetic-enhanced MRI).	15%	+ 10%
	Additional guidelines: 1. Patients must fulfill the Milan criteria at the time of upgrade in 3-monthly steps. 2. Patients initially: - inside the Milan criteria and, after treatment with one lesion <2cm or no lesion at all at time of request, are still considered to be transplant patients.		
Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Polycystic liver disease (PLD)	*Listing criteria:* 1. Massive PLD (total Cysts/Parenchyma >1) and complication(s), that can exclusively be treated by liver transplantation;		

[99] List approved by Ministry of Health and social welfare (M.Busic)

	2. clinically apparent liver disease due to massive PLD, incl. weight loss, ascites, portal hypertension; 3. Failure of non-transplant related interventions or contraindications for further non-transplant related interventions; 4. Contraindications for non-transplant related interventions, fulfilling criteria 1 and 2.		
	exceptional MELD criteria (1 or more in combination with all listing criteria): 1. Ascites or variceal bleeding; 2. Budd-Chiari-like-Syndrome with hepato-venous outflow obstruction due to cysts (CT/MRI, Venography); 3. Ascites complicating cyst fenestration procedures; 4. Severe malnutrition (decreased mid-arm circumference in the non-dominant arm: men <23.8 cm, women: <23.1 cm 5. Dialysis dependency in combination with one criterion (1-4); 6. Creatinine-Clearance 20-30ml/min in combination with one criterion (1-5).	10%	+10%
Primary Hyperoxaluria Type 1 (PH1)	*Listing criteria:* AGT deficit proven in liver biopsy or phenotypically and confirmed by genetic analysis showing a homozygous or heterozygous mutation for primary hyperoxaluria type 1[100]		
	Registration for pre-emptive liver transplantation, no significant renal injury.	10%	+ 10%
	Registration for combined liver+kidney transplantation, no end-stage renal insufficiency.	10%	+ 10%
	Patients ≥1 yr and combined liver+kidney transplantation with end-stage renal insufficiency and renal replacement therapy.	15%	+ 10%
Persistent hepatic dysfunction (including "small for size"-syndrome) with indication for retransplantation. This SE replaces the current SE "small for size syndrome".	*exceptional MELD criteria (≥3 criteria):* 1 Less than 3 months after liver transplantation.; 2. Hyperbilirubinemia ≥10 mg/dl, no proof of rejection/biliary duct obstruction; 3 Non-anastomotic bile duct strictures documented by MRI or ERCP.; 4. INR ≥ 1.5; 5. Ascites;	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
Cystic fibrosis	Liver transplantation, FEV1 <40%	10%	+ 10%
Familial Amyloidotic Polyneuropathy (FAP)	*exceptional MELD-criteria (1 and 2 in combination with 1 or more criteria from 3-6):* 1. Biopsy with proof of amyloid deposits in an organ; 2. Proof of TTR gene mutation (DNA analysis or mass spectrometry (Val30Met vs. Non-Val30Met)).	15%	+ 10%
	Additional: 3. Neurologic symptoms or modified Polyneuropathy Disability (PND) Score <IIIb; 4. Modified BMI (mBMI) >700		

[100] R-LAC 03.13 regarding genetic analysis implemented for Belgium, Croatia, Hungary, Luxembourg, the Netherlands and Slovenia as of December 15, 2014, for Austria as of September 12, 2015

	[mBMI=(weight [kg]/length [m]^2)*S-Albumin [g/L]]; 5. In case of liver transplantation only: no life-threatening rhythm disorders and/or cardiomyopathy with EF<40% ± NYHA II symptoms; 6. In case of cardiac involvement and left ventricular wall thickness >12 mm combined heart-liver transplantation should be evaluated; 7. FAP liver should, whenever possible, be used for Domino liver transplantation.		
Hepato-pulmonary syndrome (HPS)	*exceptional MELD-criteria:* 1. Proof of liver disease; 2; PaO2 <60 mmHg at rest (sitting/ supine ambient air); 3. Proof of intrapulmonary shunt and exclusion of intracardiac shunts by contrast-enhanced echocardiography; 4. No alternative pulmonary disease to explain hypoxemia.	15%	+10%
Porto-pulmonary hypertension (PoPH)	*exceptional MELD-criteria:* 1. Proof of underlying liver disease; 2. PAP: 25 < PAPm < 35 mmHg (with or without therapy);; 3. Pulmonary vascular resistance (PVR) ≥240 dyn.s.cm^{-5} 4. Pulmonary capillary wedge pressure (PCWP) ≤15 mmHg. 5. All mentioned values have to be documented by right heart catheterization.	25%	+ 10%
Cholangiocarcinoma	1. Biliary strictures in cholangiogram and biopsy and/or cytology with proof of neoplasia (aneuploidy considered to be neoplasia); 2. Tumor unresectable due to technical considerations or underlying liver disease; 3. Lesion (CT/MRI) <3cm in diameter; 4. no intra- or extrahepatic metastases in CT/MRI (thorax, abdomen), no regional lymph nodes involved (exclusion via laparatomy); 5. Centre should operate according to ratified protocol.	10%	+ 10%
Hereditary hemorrhagic teleangiectasia (Rendu-Osler-Weber-Syndrome)	*exceptional MELD criteria (*All listing criteria have to be met *):* 1. Symptomatic involvement of the liver (shunts, abscess, destructive cholangitis, liver necrosis) 2. High output congestive heart failure; 3. Cardiology report stating that high output congestive heart failure is primarily due to liver involvement and can therefore be cured by liver 4. Acute liver failure due to hemorrhagic teleangiectasia (Rendu-Osler-Weber-syndrome) transplantation	15% Meld 40	+10% Meld 40
Hepatic hemangioendothelioma	*exceptional MELD criteria (*All listing criteria have to be met *):* 1. Histopathology evidence for hepatic hemangioendothelioma: limited cell density positive immunohistochemical staining of factor-VIII- related antigens	15%	+10%

	on endothelial cells.		
	Additional guidelines: 1. Patient has to be on the liver transplant waiting list for at least one year.		
Biliary sepsis	*exceptional MELD criteria (*All listing criteria have to be met *):* 1. At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions) 2. Septicemia in spite of antibiotic therapy (i.e. source of infection cannot be eliminated)	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
	Additional guidelines: 1. Biliary sepsis can only be treated by liver transplantation		
Primary sclerosing cholangitis (PSC)	*exceptional MELD criteria (*At least two criteria have to be met *):* 1. At least two spontaneously occurring septic episodes within 6 months (not due interventions, not treatable by interventions) 2. Splenomegaly > 12 cm; 3. Body Mass Index-Reduction > 10% within 12 months.	Match MELD corresponding to a 3-months mortality calculated as the sum of: a) 3-month mortality on the Lab MELD plus; b) 20% 3-months mortality	
	Additional guidelines: 1. PSC has to be diagnosed according to standard radiology criteria		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	100%	

5.10.7 Hungary[101]

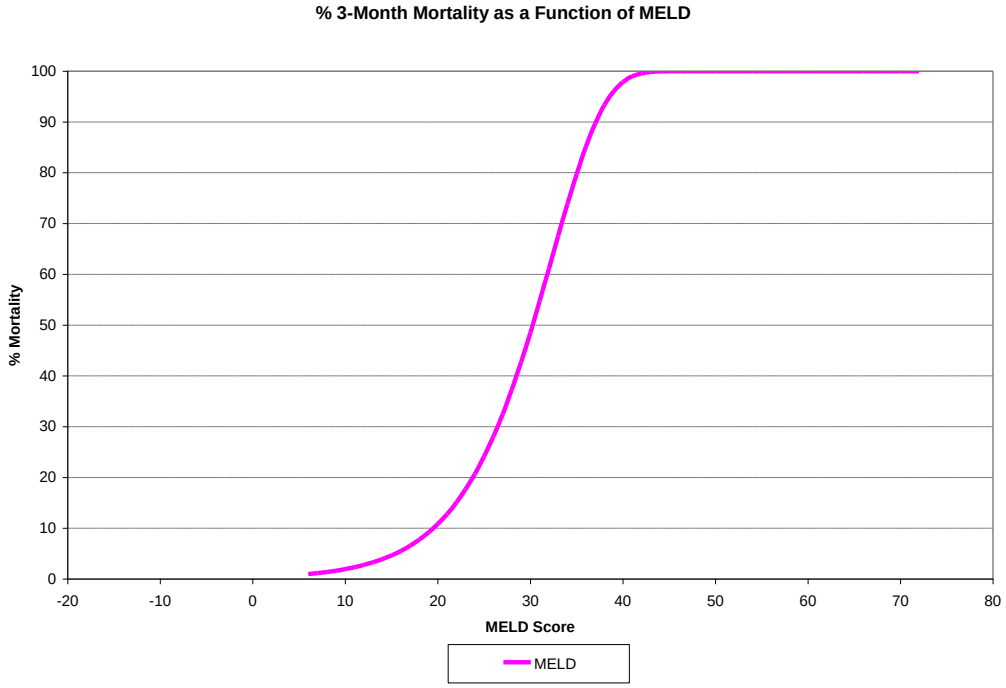
Non-metastatic hepatoblastoma	No longer applicable. A request for HU status can be done directly.		
Urea cycle disorder/organic acidemia	No longer applicable. A request for HU status can be done directly.		
Hepatic artery thrombosis	Patient diagnosed with HAT post transplantation not fulfilling the criteria for HU	100%	

[101] Standard Exceptions implemented on May 17, 2016

5.11 Addendum B – MELD equivalents

In order to assign a MELD score equivalent in patients eligible for an (N)SE exceptional MELD, the following calculation tables is applied[102].

5.11.1 Graph



[102] Based on UNOS data (June 2006).

5.11.2 Table

MELD score	3-mo mortality equivalent
20	10%
22	15%
24	20%
25	25%
26	30%
28	35%
29	40%
29	45%
30	50%
31	55%
32	60%
33	65%
33	70%
34	75%
35	80%
36	85%
37	90%
39	95%
40	100%

5.12 Forms

All forms can be found and downloaded from the section ‘Forms’ of the Library of the member site at www.eurotransplant.org.

5.13 Addendum C - reMELD-Na

In 2023, the ELIAC decided to start a two-track policy in the renewal of the UNOS MELD liver allocation:

1) Switch from the current UNOS MELD to reMELD-Na[103] as the results are superior to the UNOS MELD and already validated within Eurotransplant;
2) Simultaneously validate new possible allocation models (such as GEMA, UK transplant benefit etc.)

Eurotransplant is now preparing for the implementation of reMELD-Na, with the following steps:

1) **Implementation of reMELD-Na calculator**
The reMELD-Na calculator will be available in the MELD and ENIS Next application, providing the reMELD-Na score upon each UNOS MELD update. Please note that the reMELD-Na score is shown purely for informational purposes, the reMELD-Na score is not yet used in the liver allocation.

2) **Mandatory entry of serum sodium**
Upon each UNOS MELD update, the entry of serum sodium is mandatory for all non-German recipients.
After the serum sodium value is entered during a UNOS MELD update, the reMELD-Na score will be calculated in addition to the UNOS MELD score. The entry of the serum sodium value is no longer optional. If no serum sodium value is provided, no UNOS MELD update is possible.
For the entry of serum sodium values the same rules apply as for the entry of the current UNOS MELD lab values, as can be found in the *ELAS Manual 5.5.1.2.2 (Lab) data provided* and the *MELD Manual 5 Recertifying MELD scores*.
Since the entry of serum sodium is now mandatory, an audit will take place by Eurotransplant. The serum sodium value is stored until a new entry takes place. Upon the planned implementation of the reMELD-Na score, the available serum sodium value will be used in the calculation of the reMELD-Na score and in the liver allocation.

3) **Planned implementation of reMELD-Na score** on March 25, 2025. See *5.13.2* below.

5.13.1 Calculation of reMELD-Na[104]

The reMELD-Na score is calculated as follows:

$$7.85 + 9.03 * \log(crea) + 2.97 * \log(bili) + 9.52 * \log(INR) + 0.392 * (138.6 - sodium) - 0.351 * (138.6 - sodium) * \log(crea)$$

5.13.1.1 Caps for MELD biomarkers

For UNOS MELD, currently a lower cap of 1.0 is used for creatinine, bilirubin, and the INR. Serum creatinine is additionally capped from above by 4.0 mg/dl.

103 Goudsmit et al. Refitting the Model for End-Stage Liver Disease for the Eurotransplant Region. Hepatology. 2021 Jul;74(1):351-363. doi: 10.1002/hep.31677.

104 Please note that the formula differs slightly from the formula in the article by Goudsmit et al, as this was published with an error. The formula above is correct and has been confirmed by Goudsmit by email.

For ReMELD-Na, the following lower and higher caps are used when calculating the score:

- Creatinine: 0.7-2.5 mg/dl
- INR: 1.0[105]-2.6
- Bilirubin: 0.3-27 mg/dl
- Sodium: 120-138.6 mmol/l

- Sodium can be entered with 1 decimal.
- For candidates who received dialysis twice a week before listing, creatinine is calculated with an upper cap of 2.5 mg/dl by the system. The serum creatinine should be entered as listed on the lab sheet.

5.13.1.2 Limits for the MELD scores

Currently:
- Minimum possible UNOS MELD: 6
- Maximum possible UNOS MELD: 40

Under ReMELD-Na:
- Minimum possible ReMELD-Na: 1
- Maximum possible ReMELD-Na: 36

The maximum and minimum score for ReMELD-Na are different from the UNOS MELD because new caps for the biomarker values are introduced, and because the formula uses different coefficients.

5.13.2 Implementation of reMELD-Na score

The planned implementation of the reMELD-Na score is on March 25, 2025. On this date, all UNOS labMELD, SE/NSE, Study NSE's with extra exceptional points and pedMELD scores will be converted to reMELD-Na scores.
Please note: Should no serum sodium value be available for the UNOS labMELD score at this date, no reMELD-Na score can be calculated, and the patient will receive a downgraded reMELD-Na score of 1.

Currently, when a candidate does not recertify their MELD score in time, they receive a downgraded UNOS MELD score of 6. After the implementation of the reMELD-Na score, a candidate will receive a downgraded reMELD-Na score of 1 when their reMELD-Na score is not recertified in time.

5.13.2.1 S-curve for PED-MELD and (N)SE mortality equivalents

All exception points within Eurotransplant are defined in terms of mortality equivalents. For instance the SE HCC in all countries (except the Netherlands) leads to an initial mortality equivalent of 15%, which increases every 90 days with 10 percentage points. For allocation, these mortality equivalents are currently translated to the UNOS-MELD scale. This transformation is based on the following formula:

[105] INR of 1.0 as lower limit will be used in practice, whereas an INR of 0,1 was used in the formula. Decided in the ELIAC of 02-10-24

$$S_{90} = 0.98037 \text{ ^ } \exp\,(0.17557(MELD - 10))$$

This formula comes from a Cox proportional hazards model with adjustment for a MELD score. Fitting the same model for ReMELD-Na scores has yielded the following revised formula:

$$S_{90} = 0.9745 \text{ ^ } \exp\,(0.2216(ReMELDNa - 10))$$

A graph plotting both S-curves and showing a conversion table between mortality equivalents and the UNOS-MELD / ReMELD-Na score is included in the last paragraph of this document.

All SE scores, NSE scores, Study NSE's with extra exceptional points and pediatric MELD scores will be updated to the new ReMELD-Na S-curve formula.

5.13.2.2 Threshold blood type 1 / 2 compatibility rules

Currently, blood type O donors may be allocated to blood type B candidates in case the candidates' MELD score ≥30 (which corresponds to a 50% mortality equivalent for UNOS MELD). See *5.4.2* and *5.4.3*.
This threshold has to be changed to a ReMELD-Na score of ≥25 (the 50% mortality equivalent for ReMELD-Na) to maintain access to transplantation for high-MELD type B candidates.

5.13.2.3 MELD recertification schedule

Recertification of MELD is currently based on the following schedule as can be found in paragraph 5.1.1.3.2.1:

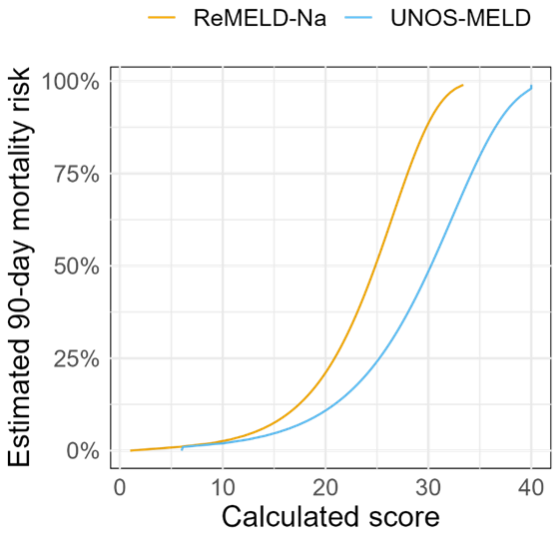
MELD	lab MELD expires after	Notification before expiry	Expiry date of lab values at data entry
MELD ≥25	7 d	2 d	not older than 48 h
MELD ≤24, >18	30 d	7 d	not older than 7 d
MELD ≤18, ≥11	90 d	14 d	not older than 14 d
MELD ≤10	365 d	30 d	not older than 30 d

Based on the revised 90-day mortality equivalents, the schedule will be:

ReMELD-Na Score	lab MELD expires after	Notification before expiry	Expiry date of lab values at data entry
ReMELD-Na ≥ 21	7 d	2 d	not older than 48 h
ReMELD-Na ≤ 20, ≥ 16	30 d	7 d	not older than 7 d
ReMELD-Na ≤ 15, ≥ 10	90 d	14 d	not older than 14 d
ReMELD-Na ≤ 9	365 d	30 d	not older than 30 d

5.13.2.4 90-day mortality equivalents under the revised S-curve

All SE scores, NSE scores, Study NSE's with extra exceptional points and pediatric MELD scores are coupled to 90-day mortality equivalents. MELD scores corresponding to these mortality equivalents are calculated based on the survival curves (S-curves). Technically, these S-curves are implemented as formulas at ET. The plot below shows in orange the ReMELD-Na scores and in blue the UNOS-MELD scores corresponding to each mortality equivalent. For reference, ReMELD-Na scores per 5%-mortality equivalent are included in the Table below.



3-mo mortality equivalent	UNOS MELD score	reMELD-Na score
10%	20	16
15%	22	18
20%	24	20
25%	25	21
30%	26	22
35%	28	23
40%	29	23
45%	29	24
50%	30	25
55%	31	25
60%	32	26
65%	33	27
70%	33	27
75%	34	28
80%	35	29
85%	36	29
90%	37	30
95%	39	31
100%	40	36