

Frequently Asked Questions

SLK Policy--General

1) Why do we need an SLK policy?

Candidates waiting for a liver and a kidney transplant are currently prioritized for both organs before pediatric and adult kidney-alone transplant candidates if the deceased donor is in the same Donation Service Area (DSA). Right now, the kidney is not allocated based on a candidate's kidney function. Instead, geographic proximity between the liver-kidney candidate and the donor and the candidate's medical urgency for the liver are the factors used for allocating the kidney.

The lack of medical criteria is counter to requirements in the OPTN Final Rule specifying that organ allocation policies be based on sound medical judgment and standardized criteria.

There is also a lack of consistency for *regional* liver-kidney, as deceased donor liver allocation prioritizes candidates with a certain medical urgency status or Model End Stage Liver Disease Score (MELD) score for regional allocation but regional liver-kidney allocation was not required for these candidates. Each of these issues concerned the liver transplant community.

2) How was this new policy developed?

This new policy is the result of over a decade of work. Since the MELD score was introduced into deceased donor liver allocation policy in 2002, SLK transplants have significantly increased in the United States. Concerns about the lack of clear rules for SLK allocation have increased alongside the growing number of SLK transplants.

In 2006 and 2007, American Society for Transplantation (AST) and the American Society of Transplant Surgeons (ASTS) held a consensus conference to discuss and develop recommendations for SLK medical listing criteria. Following the conference, the Kidney and Liver Committees jointly sponsored a 2009 public comment proposal that adopted some of those recommendations. The majority of the OPTN/UNOS regions and individuals who offered feedback were supportive of the 2009 proposal. However, several national professional groups, notably ASTS, the National Kidney Foundation (NKF), and the American Urological Association (AUA) opposed portions of the proposal for different reasons. ASTS' main concern was that the medical criteria established was too strict. NKF's and the AUA's main concerns were that the medical criteria was too loose and the additional priority on the kidney waiting list would impede access for kidney-alone candidates.

Further complicating the effort, many of the proposed changes involved complex and expensive IT programming—mostly due to the vast number of kidney allocation policy variances that existed at the time and the unknown factor of when the new kidney allocation system (KAS) would be approved and implemented. Because of these concerns, the committees decided not to move forward with sending the 2009 proposal to the Board

of Directors for approval. Once the new KAS was approved by the Board of Directors in June 2013, the Committee formed a working group to discuss possible changes.

The working group met throughout 2013 and 2014 to review previous proposal work, 2009 public comments, recent literature on SLK and kidney after liver transplants, and available OPTN data. In December 2014, the working group agreed on a set of recommendations. They presented these recommendations to the 11 OPTN regions and distributed them to several of the professional transplant societies who commented on the 2009 proposal. The Committee made some adjustments in response to the pre-public comment feedback and sponsored another public comment proposal in the fall 2015.

The working group and Committee reviewed public comments received on the fall 2015 proposal, made 15 changes in response, and distributed the updated proposal for another round of public comment in Spring 2016. The Board approved the new policy in June 2016.

- 3) How will the committee track the impact of the new rules once they go into effect?
This policy will be formally evaluated approximately 6 months, 1 year, and 2 years after implementation.

The following questions, and any others subsequently requested by the Committee, will guide how we will evaluate the policy change after it is implemented:

- Has the SLK medical eligibility criteria affected the number of SLK transplants?
- Has the combination of SLK medical eligibility criteria and the “safety net” resulted in a net decrease, increase, or no change in the number of kidneys going to liver recipients?
- Has there been a change in the number of registrations for kidney within a year of a liver transplant?
- Has the policy increased access to transplants and decreased mortality rates for those registered for kidney within a year of a liver transplant?
- Has the number of living donor kidney transplants post liver transplants remained stable?

The following metrics, and any others subsequently requested by the Committee, will be evaluated to compare performance before vs. after the implementation of the new policy:

- The number of SLK transplants, overall, by geographic distribution (local, regional, national) and pediatric vs. adult
- The distribution of SLK transplants by diagnosis confirming SLK eligibility (CKD with $GFR \leq 60$ mL/min for greater than 90 consecutive days -- dialysis vs. $GFR/CrCl \leq 30$; sustained acute kidney injury; metabolic disease) and more granular GFR groups, where appropriate (post implementation only);
- The number of candidates registering for a kidney within a year of a liver transplant;

- The number of candidates registering for a kidney within a year of a liver transplant by candidate's eligibility for kidney allocation "safety net" priority (post implementation only);
- The number of transplants for kidney candidates who were reported to be eligible for kidney allocation "safety net" priority;
- Waiting list mortality and transplant rates for kidney candidates added to the waiting list within a year of liver transplant;
- Number of living donor kidney transplants post liver transplants.

The Committee will also evaluate the effect of the policy on specific patient populations (pediatric, racial and ethnic minority) and geographic location (OPTN region, DSA).

SLK Medical Eligibility Criteria

- 4) Do the new medical criteria apply to pediatric SLK candidates?
No. Pediatric liver-kidney candidates (those registered on the liver waiting list before their 18th birthday) must only be registered on both the liver and kidney waiting lists to qualify for an SLK transplant.
- 5) Does the medical diagnosis from the 'transplant nephrologist' have to be the primary physician listed with UNOS?
No. Any transplant nephrologist can confirm the diagnosis in the medical record.
- 6) Is it appropriate to use a diagnosis from a nephrologist from a different transplant program?
Yes. For example, if the candidate is listed at multiple transplant programs and one program would like to use the documented diagnosis from another program where the candidate is registered, the program would be in compliance with the policy.
- 7) Is the "Liver-Kidney (SLK) Diagnosis Confirmation" form located in UNet required to document the transplant nephrologist diagnosis of CKD, acute kidney injury, or metabolic disease?
No, it is not required, but you must locate some form of documentation in the medical record before entering the transplant nephrologist's name in UNet.
- 8) Is the transplant nephrologist's signature required to meet the policy requirement?
No, you do not need a signature, but documentation of the transplant nephrologist's diagnosis must be in the medical record.
- 9) Is a center required to list a candidate for an SLK transplant if they meet the medical eligibility criteria?
No. Transplant programs may still decide which candidates to list for transplant.
- 10) Are my candidates required to meet this criteria before I can register them on the kidney waiting list?

No. Your program can still decide which candidates to list for a kidney transplant. The new rules will be used to determine eligibility for a kidney offer at the time of allocation.

- 11) Is this new policy requiring candidates to meet SLK medical eligibility criteria expected to increase or decrease the number of SLK transplants?

Based on review of available data, there is a suggestion that the new medical criteria will result in a decrease of SLK transplants. Although data isn't available that allows for an "apples to apples" comparison on how many SLK recipients would have met the medical eligibility criteria (some of the newly proposed criteria is not currently collected on liver recipients), UNOS research staff used a working definition of ESRD (dialysis <2 months or creatinine <2.5) to model the medical eligibility criteria. Using that definition, they found that 15-30% of current SLK recipients would not have met medical criteria.

Questions regarding Chronic Kidney Disease (CKD) eligibility

- 12) Why does the policy not require a specific type of measurement for GFR?

The Committee considered but did not adopt a requirement for a uniform method for measuring and calculating GFR. The majority of the Committee was concerned with requiring a uniform measurement because programs use different tools, there is sufficient debate about the accuracy of differing measurements, and such a new requirement would be difficult and complex to monitor for compliance. Additionally, when assigning waiting time points in kidney alone allocation, we do not require a specific type of GFR measurement.

Questions regarding acute kidney injury eligibility

- 13) For acute kidney injury, will centers have to obtain a new GFR from liver recipients every 7 days?

Yes. This requirement helps your liver transplant program demonstrate that a candidate has consistent kidney dysfunction over the period of six weeks before the SLK transplant. The liver transplant representatives on the SLK working group offered that this shouldn't be burdensome to liver programs because OPTN policy requires liver programs to update MELD status every 7 days (for patients with MELD at least 25). The working group and Kidney Committee discussed whether to change the requirement for candidates with MELD less than 25, but the groups concluded that it would be rare when a liver candidate with sustained acute kidney injury and a MELD < 25 will be a liver-kidney candidate because the creatinine clearance is a part of the MELD criteria. In those rare cases where a candidate does exist, the Kidney Committee representatives felt the liver transplant program needed to bear the burden to report kidney transplant eligibility for the candidate.

- 14) When entering data into the new fields for SLK qualification, the field for eGFR does not accept "<15" which is the standard result provided by our lab. How should I report eGFR? In cases when the eGFR test result is provided as a range, we recommend working with your laboratory to get a more precise value. If the laboratory cannot provide a more precise value, please report any value within the range. This recommendation is limited only to eGFR results provided as a range with a maximum value that does not exceed 15.
- 15) How do you define six weeks? Does the last qualifying event and the first qualifying event have to be 42 days apart? Do we just need six qualifying events in six different weeks? There is no connection between sequential "calendar" weeks (i.e. Sun-Sat) and the requirement to test every 7 days. No more than 7 days can elapse between qualifying labs. The clock for 7 days gets reset with every test a center reports, and ultimately the patient will have to have qualified for a continuous period of 6 weeks (42 days) before becoming eligible to receive an SLK.

Once you have reported the required data every seven days for a period of six consecutive weeks (counted from the first reported test/treatment date), your candidate becomes eligible.

- 16) After I have confirmed my candidate's eligibility for 6 weeks, do I still need to test and report lab values and dialysis treatment? Yes. You need to confirm eligibility on a continual basis until your candidate receives an SLK transplant. This demonstrates that your candidate has had consistent kidney dysfunction for six weeks before the SLK transplant.
- 17) What happens if my candidate misses a week of labs? If the eligibility isn't confirmed at least once every seven days, your candidate will be marked as ineligible to receive a kidney with their liver offer and the 6-week time period will restart.
- 18) If I obtained the GFR measurement during the 7-day period but didn't report it on time and my candidate's eligibility has expired, will I be able to report it for my candidate to become eligible again? Yes, the liver waiting list fields will allow centers to enter previous test results. Liver programs must document the measurement in the medical record.
- 19) If my transplant program obtains multiple test values within the 7-day period, do we have to report all tests? No. You are not required to report all values; only those values that your program wants considered.
- 20) Is there a 48 hour time period for turn-around of loading these labs? Policy does not specify a turnaround time for reporting the required lab data. However, the candidate's eligibility will expire if the required information isn't confirmed at least once every 7 days for the last six weeks. In order to remain eligible, no two tests or treatment

dates entered in the system can be greater than 7 days apart. If you don't report the information on time, the system will still allow you to report an earlier test. As long as the test dates still meet the medical eligibility criteria, your candidate will display as eligible.

21) Will my adult candidate automatically become inactivated if they don't meet the SLK medical criteria?

The system will indicate to OPOs that the candidate is not eligible to receive a kidney offer with a liver offer. It will not affect your candidate's eligibility for a liver offer.

22) Am I required to update both the liver and kidney waiting list records in UNet every 7 days?

No. You only need to update the liver candidate record in UNet at least once every 7 days.

SLK Allocation

23) How does this proposal impact multi-organ allocation?

If an OPO procures a kidney along with other organs, and there is a local candidate highest on heart, lung, or liver match also listed for a kidney or a compatible candidate in the first five classifications on the kidney-pancreas match, the OPO must first offer the kidney as a multi-organ offer. That rule has not changed. And, like today, if you have more than one highest ranking multi-organ candidate (for instance, on the heart match run and liver match run) who are also listed for a kidney, the OPO will make the decision about which combination to offer. There are now three policies that deal with multi-organ offers and this new SLK policy makes it clear that the OPO must decide which combination to offer, but they must offer to a multi-organ candidate first in this instance before allocating the kidney using the kidney alone match run. The three multi-organ policies at play here are:

- 1) The general catch all policy dealing with kidneys offered with a lung or heart (Policy 5.10.C)
- 2) *This new Liver-Kidney Allocation policy (new section 9.7) and*
- 3) *The Kidney-Pancreas Allocation policy (Policy 11.4.A)*

So, once the OPO makes the decision as to which combination to offer, the OPO must follow the policy for that particular combination.

If the candidate highest on the liver match is a liver-kidney candidate and the OPO decides to offer as a liver-kidney combination, then the OPO must offer the kidney and liver according to the new rules.

These new rules require adult liver-kidney candidates to meet certain medical eligibility criteria to receive the kidney offer with the liver.

To be clear, this new policy does *not* mandate that an OPO offer the kidney with the liver before offering the kidney as part of another multi-organ combinations. This policy adds one additional class of liver-kidney candidates that the OPO is required to offer to *before*

allocating the kidney using the kidney alone match—regional liver-kidney candidates who meet medical eligibility criteria and have a MELD of at least 35 or status 1A. These are candidates who are prioritized for regional liver shares according to the deceased donor liver policy. This requirement simply makes the liver-kidney policy consistent with deceased donor liver policy in terms of priority for regional sharing.

24) When is the OPO required to allocate the kidney with the liver (before allocating the kidney using the kidney alone match run)?

There are three scenarios in which the OPO must offer the kidney with the liver before allocating the kidney to the kidney-alone list. The liver match run will indicate to OPOs when allocation is required.

If a liver-kidney candidate...	And the donor is...	Then the OPO:
is highest on the liver match run and was registered on the liver waiting list before their 18 th birthday (pediatric)	In the same DSA, regional, national	must offer the kidney with the liver before allocating using the kidney alone match
is highest on the liver match run, an adult candidate, and meets the medical eligibility criteria	In the same DSA	must offer the kidney with the liver before allocating using the kidney alone match
is highest on the liver match run, an adult candidate, meets the medical eligibility criteria, and has a MELD of at least 35 or status 1A	In the candidate's region	must offer the kidney with the liver before allocating using the kidney alone match

Implementation timeline and applicability

25) When will the new rules go into effect?

The new rules become effective August 10, 2017.

26) When the policy is implemented, will it apply to all SLK candidates or just those added to the waiting list after implementation?

The new policy will apply to all liver-kidney candidates upon implementation, meaning that all adult SLK candidates will be required to meet the new medical eligibility criteria.

27) What if the OPTN/UNOS liver allocation policy regarding the MELD threshold for broader sharing of livers changes?

In this instance, the Kidney Committee would review the policy and likely propose changes to ensure the allocation rules for liver-kidney allocation are consistent with that of liver allocation rules.

The Kidney “Safety Net” (new match classification for liver recipients on the kidney waiting list)

28) What is the new kidney “safety net”?

Because there was no definitive data on which to develop the SLK medical eligibility criteria (it was developed based on some evidence and clinical consensus between liver and kidney transplant surgeons and specialists), the Board approved the creation of a new priority match classification on the kidney-alone waiting list for liver recipients who experience kidney dysfunction and dialysis dependency in the year after their liver transplant.

Required medical criteria:

This classification gives priority to a kidney candidate if both of the following criteria are met:

1. *The candidate is registered on the kidney waiting list before the one-year anniversary of their most recent liver transplant date.*
2. *On a date that is at least 60 days but no more than 365 days after the candidate’s liver transplant date, at least one of the following criteria is met:*
 - *Candidate’s measured or calculated creatinine clearance (CrCl) or glomerular filtration rate (GFR) is less than or equal to 20 mL/min.*
 - *Candidate is on dialysis.*

29) Why does candidate priority start at 60 days after liver transplant?

There Board agreed with the recommendation that there should be some period of waiting after liver transplant to determine whether kidney function would recover after the liver transplant.

We considered the following data to help determine the safety net prioritization:

- Of those liver recipients listed for a kidney, 19% of them were listed in the first year after their liver transplant.
- Of those liver recipients who later received a kidney transplant, 93% of them received their kidney transplant more than a year after their liver transplant. 40-41% of them received their kidney transplant more than 9 years after their liver transplant.
- A 2013 AJT publication, which found that the risk of newly developed ESRD is at its highest in the 6 months after liver transplant.

30) Can you provide some scenarios to help our program understand eligibility for the safety net priority and the timeframes for confirming that the kidney candidate is still eligible?

Policy language:

When the transplant program reports that the candidate meets the criteria for this classification, the candidate will remain at this classification for 30 days from the date of the qualifying test or treatment. If the transplant program reports additional qualifying tests or

treatments, then the candidate will remain at this classification for 30 days from the most recent date of the test or treatment. If the transplant program reports that the candidate meets the criteria for 90 consecutive days, then the candidate will remain at this classification until the candidate is removed from the kidney waiting list.

Here, we will use kidney candidate “Joe” to walk through a few scenarios with the safety net.

Kidney candidate Joe has been on the kidney waiting list since 2015 when he also received a liver transplant. New data pertaining to the safety net priority was entered for Joe on the kidney waiting list in June 2017. Based upon the data entered, Joe met the medical criteria for 90 consecutive days, making Joe eligible for “safety net” priority until he is removed from the kidney waiting list. The new safety net priority is implemented in August 2017.

Scenario #1: Liver recipients registered before the new policy is implemented.

Q: Is Joe eligible for the new safety net priority? How does the new priority apply to candidates on the kidney waiting list before the policy is implemented?

A: Yes, Joe is eligible for the new safety net priority. Once the new policy is in effect, all liver recipients on the kidney waiting list (except for those who received a liver-kidney transplant) will be eligible for this new priority if they meet the medical criteria in the timeframe specified by the policy and the transplant program has reported the data.

Scenario #2: SLK recipients

Q: What if Joe had received an SLK transplant in 2015 but later experienced kidney non-function. Will he still be eligible to receive the safety net priority?

A: If Joe experienced immediate and permanent non-function of the kidney (as defined in policy 3.6.B.i: *Non-function of a Transplanted Kidney*), he will still be eligible for the safety net priority. Otherwise, SLK recipients are not eligible for safety net priority.

Scenario #3: Waiting time transfers

Q: What if Joe is registered at a second transplant program in 2016 and he now wants to transfer his primary waiting time to the second program? Will he be able to transfer his safety net priority too?

A: Yes. Since Joe has met the 90 consecutive day requirement, his eligibility for this new requirement will be included in the transfer to the second transplant program.

Scenario #4: Living liver donor transplants and liver with other organs

Q: What if Joe received a heart-liver transplant or a living liver donor transplant in 2015? Does the new priority only apply to liver-alone recipients who meet the criteria? Will living liver donor recipients also be eligible for the new priority if they meet the medical criteria?

A: The new priority applies to all liver recipients, including living donor liver recipients and those who received a liver transplant along with another organ, except for SLK recipients.

SLK recipients will only be eligible for the safety net if they meet the medical criteria and experience immediate and permanent non-function of the kidney within 90 days of their SLK transplant.

Scenario #5: Additional liver transplants

Q: What if Joe needs another liver transplant and receives one in September 2017? Will this affect his eligibility for the kidney safety net priority?

A: No. Joe will remain eligible until removed from the *kidney* waiting list. (Although, in this scenario, it is likely that he would be eligible for and would receive an SLK transplant instead).

Scenario #6: Foreign liver transplants

Q: What if Joe received his liver transplant outside of the United States?

A: Does the new priority apply to liver recipients who were transplanted abroad?

Yes, as long as the liver recipient has documentation and meets the medical criteria.

A new utility will be included as part of the implementation of this new policy that will enable programs to register foreign liver transplants for purposes of the new priority.

Let's use another case to look at scenarios dealing with the safety net timeframes.

In August 2017, the new safety net priority is implemented. On January 1, 2018, "Jake" receives a liver transplant. Jake is on the kidney waiting list and continues to need dialysis after his liver alone transplant.

Timeframe eligibility questions:

Scenario #7:

Q: If Jake continues to need dialysis or has a GFR at or below 20 mL/min, when will he become eligible for the safety net priority?

A: If your program reports that Jake has had dialysis treatment or a GFR at or below 20 mL/min, his earliest eligibility date will be March 2, 2018. If your program reports that the dialysis treatment date or GFR test date was on March 2, UNet will count Jake as eligible and he will appear in this classification on kidney match runs for the next 30 days (through April 1, 2018).

Scenario #8:

Q: What if the dialysis treatment or test value occurred on March 2 but our transplant staff did not enter the data on the same day. Will they be able to report the March 2 treatment or test on March 5?

A: Yes, UNet will allow you to provide past dates for dialysis and GFR measurement. The 30-day eligibility will be based on the treatment or test date you entered.

Scenario #9:

Q: What if our transplant program does not enter another qualifying test or treatment date on or before April 1? In other words, what happens after the 30 days expires if we do not enter any qualifying test or treatment dates?

A: Jake will not be eligible for the additional safety net priority on the kidney match run (he will not show up in this kidney match “safety net” classification). He will, however, be eligible to appear in other classifications based on medical factors and donor compatibility.

In other words, even if Jake is no longer eligible for the safety net priority, this does not affect his status on the kidney waiting list and will not affect his ability to appear on kidney match runs. It only affects whether he will appear in this particular match classification.

Scenario #10:

Q: What if Jake becomes ineligible after April 1 because no additional treatment or test dates were entered but our transplant program reports an additional treatment or test that occurs on April 10?

A: Jake will again become eligible for the safety net priority for an additional 30 days (through May 10). In other words, as long as Jake is still within the 60-365 day after liver transplant timeframe, a qualifying treatment or test date will result in 30 days of eligibility for the safety net priority. If Jake has been eligible for 90 consecutive days, he will remain eligible until you remove him from the kidney waiting list regardless of whether you report additional treatment or test dates.

Scenario #11:

Q: What if Jake does not have a qualifying test or treatment until December 15, 2018?

A. Once your program reports this treatment or test date, Jake will become eligible for 30 days (through January 14, 2019). At this point, Jake will be past the one year anniversary for his liver transplant. As such, it is important for your program to report qualifying test and treatment values before or on January 14, 2019 (and subsequently until the 90 consecutive day criteria are met) in order for Jake to remain eligible.

31) Where does the new safety net match classification fall in relation to others on the kidney match run?

See below where the classification falls in Sequences B-D of the deceased donor kidney allocation match classifications.

Sequence A KDPI ≤ 20%	Sequence B KDPI >20% but <35%	Sequence C KDPI ≥35% but ≤85%	Sequence D KDPI >85%
Highly sensitized	Highly sensitized	Highly sensitized	Highly sensitized
0-ABDR mismatch	0-ABDR mismatch	0-ABDR mismatch	0-ABDR mismatch
Prior living donor	Prior living donor	Prior living donor	Local SLK safety net
Local pediatrics	Local pediatrics	Local SLK safety net	Local + regional
Local top 20% EPTS	Local SLK safety net	Local candidates	National candidates
0-ABDR mismatch (all)	Local adults	Regional candidates	
Local (all)	Regional pediatrics	National candidates	

Regional pediatrics	Regional adults		
Regional (top 20%)	National pediatrics		
Regional (all)	National adults		
National pediatrics			
National (top 20%)			

In these sequences, prioritization for liver recipients on the kidney waitlist is marked as “Local SLK safety net”. There is no priority for local liver recipients in Sequence A of the kidney match run (those kidneys with a KDPI of less than or equal to 20%). Though priority is not offered in for Sequence A kidneys, local liver recipients may still appear in Sequence A based on other medical factors.

For instance, candidates who fall into the top 20% EPTS category and have a CPRA of 99% or 100%, may fall in one of these classifications in Sequence A.

In Sequence B, the local SLK safety net prioritizes liver recipients before other local adults, but after local pediatric candidates. In Sequence C, liver recipients are prioritized before local candidates, but after prior living donors and then in Sequence D these candidates are prioritized before local and regional candidates, but after O-ABDR mismatch candidates.

32) What documentation do I need to show that my liver recipient met the medical criteria?

You are expected to provide documentation supporting any eligibility data you entered in UNet. For more details, see the evaluation plan preview.

33) When I enter data into the new fields for SLK qualification, the field for eGFR does not accept "<15", which is the standard result provided by our lab. How should I report eGFR? In cases when the eGFR test result is provided as a range, we recommend working with your laboratory to get a more precise value. If the laboratory cannot provide a more precise value, please report any value within the range. This recommendation is limited only to eGFR results provided as a range with a maximum value that does not exceed 15.

34) How many liver recipients are expected to be eligible for this new priority?

Prior data analyses performed for the Kidney Committee showed that about 50 liver recipients per year were added to the kidney waiting list within a year of the liver transplant. Updated analyses showed that over an 8.5 year period, 2.5% or about 1,200 of the 48,000 liver-alone recipients went to either be put on the kidney waiting list, put on chronic dialysis, or receive a living donor transplant within a year. 1,200 transplants into approximately 140 transplants per year.

35) Will this new priority discourage a liver recipient from seeking a living kidney donor?

The Kidney Committee reviewed data showing that about 1/3 of the kidney transplants received by liver recipients were living donor transplants. The Committee did not make any changes to accommodate this concern, mostly because any new requirement could

potentially disadvantage candidates who may have a harder time finding a living donor than others and would be very difficult for the OPTN to monitor.