# Transplant Review Guidelines for Solid Organ Transplantation (Ohio Only)

## Policy CSTRANSPT003.D

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# Application

This clinical guideline applies only to the state of Ohio. Any requests for services that are stated as unproven or services for which there is a coverage or quantity limit will be evaluated for medical necessity using Rule 5160-1-01 - Ohio Administrative Code | Ohio Laws.

In accordance with Ohio Administrative Code 5160-2-65 (L), reimbursement for all organ transplant services, except for kidney transplants, is contingent upon review and recommendation by the "Ohio Solid Organ Transplant Consortium" [The Ohio Solid Organ Transplantation Consortium (OSOTC)] based on criteria established by Ohio organ transplant surgeons and authorization from the department. Organ acquisition and transportation costs for heart, heart/lung, liver, pancreas, single/double lung, and liver/small bowel transplant services will be reimbursed at one hundred per cent of billed charges.

Prior authorization activities must be conducted in accordance with the Ohio Department of Medicaid Managed Care Provider Agreements located at: Managed Care Agreements (ohio.gov).

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# SARS-CoV-2-Vaccination

Optum supports the recommendations of the American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST) and The International Society for Heart and Lung Transplantation (ISHLT) concerning vaccination against SARS-CoV-2. Optum encourages solid organ transplant candidates to discuss the following ASTS/AST/ISHLT recommendations of their transplant team:

- Solid organ transplant recipients should be vaccinated against SARS-CoV-2, using locally approved vaccines
- Eligible household and close contacts of solid organ transplant recipients should be vaccinated against SARS-CoV-2
- Whenever possible, vaccination should occur prior to transplantation, ideally with completion of vaccine series a minimum of 2 weeks prior to transplant.
- Solid organ transplant recipients that have received 2-dose mRNA vaccine should also receive a third dose of mRNA vaccine to complete the series.

Optum understands there are many additional issues relevant to the individual member such as local prevalence of SARS-CoV-2 and its variants, personal situations relating to immunosuppression and transplant infections, and the vaccination level in the household. Decisions concerning vaccination should be made by the member in consultation with the member's transplant team.

## Reference

ASTS, AST, ISHLT Joint Statement about COVID-19 Vaccination in Organ Transplant Candidates and Recipients. November 15, 2022. Available at: 2023-11-15-ishlt-ast-asts-joint-statement-covid19-vaccination.pdf

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# Kidney Transplantation

Medical necessity determinations must comply with the definitions and principles established in Rule 5160-1-01 - Ohio Administrative Code | Ohio Laws

For multi-organ transplants such as kidney/liver, kidney/heart, and kidney/lung, patients must meet the clinical criteria for each individual organ. Criteria for non-kidney organs are defined by the Ohio Solid Organ Transplantation Consortium (OSOTC), and reimbursement for these transplants requires OSOTC review and recommendation. OSOTC criteria for non-kidney organ transplantation are available at: Review OSOTC Patient Selection Criteria | Indications & Contraindications

## General Information

- Kidney transplantation is the treatment of choice for suitable patients with end-stage kidney disease.
- Preemptive living donor transplantation is encouraged whenever possible.
- Candidates should be referred to a transplant center as soon as it appears probable that renal replacement therapy (dialysis) will be needed within the next 6–12 months (Chadban et al., 2020).
- Due to the very long wait times and the likely increased burden of comorbid conditions, patients over the age of 70 may not be considered for deceased donor transplantation by many kidney transplant programs. In many instances, while a member 70–75 years of age may not be considered for a deceased donor transplant, a center may be willing to evaluate an older patient for a living donor transplant.
    - The importance of living donation in this situation should be emphasized with the patient.
- Wait times in many parts of the country can last for years, particularly for those with blood groups O and B and those who are highly sensitized. Strategies to increase the likelihood of getting an organ include:
    - Patients should be very strongly encouraged to consider living donation and to seek out potential donors. Kidney Paired Donation/Exchange (KPD) is considered medically necessary.
    - Double-listing in another United Network for Organ Sharing (UNOS) Region with a shorter wait time should be discussed and encouraged if the patient's living situation will allow the flexibility to do this.
    - ABO incompatible transplants are considered medically necessary.
    - Desensitization protocols for highly sensitized (high PRA/panel-reactive antibody) patients are considered medically necessary.
- Candidates should be informed that placement on the cadaveric waiting list does not guarantee transplantation, since changes in their medical status may delay or preclude transplantation.
    - If a patient will have to be on a waiting list for a long time, the importance of maintaining transplant readiness by strict adherence to all advice from the transplant center, the treating nephrologist and the dialysis center should be emphasized.
- Patients with primary oxalosis with ESRD should be considered for combined liver/kidney transplant (Siegal et al., 2011; Dhondup et al., 2018).

## Indications

- When to refer (Chadban et al., 2020):
    - Kidney transplantation should be discussed with all patients with irreversible advanced chronic kidney disease (CKD).

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  - Patients with CKD without known contraindications for transplantation should be referred to a transplant program when they approach CKD stage 4 or a glomerular filtration rate (GFR) less than 30 ml/min/1.73 $m^2$.
  - Early referral will improve the chances of a patient receiving a preemptive transplant, especially those with a potential living donor; referral to a kidney transplant program does not imply immediate transplantation.
- End-stage renal disease (ESRD):
  - Chronic renal failure with glomerular filtration rate (GFR) < 20ml/min
  - Chronic renal failure on dialysis
  - Symptomatic uremia
- Anticipated ESRD as defined above within next 12 months (preemptive transplantation).
- Combined kidney/liver transplant *when at least one* the following are present: (OPTN Policy 9.9 Liver-Kidney Allocation; Table 9-17 Medical Eligibility Criteria for Liver-Kidney Allocation). See Appendix A for National Kidney Foundation (NKF) definition of chronic kidney disease (CKD).
  - Candidates with sustained acute kidney injury (AKI):
    - Dialysis at least once every 7 days for the last 6 weeks

      **AND/OR**

    - eGFR ≤ 25 mL/min at least once every 7 days for the last 6 weeks
  - Candidates with chronic kidney disease (CKD) as defined by the National Kidney Foundation (NKF) **AND** at least one of the following:
    - Regularly administered dialysis as an end-stage renal disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting
    - eGFR ≤ 30 mL/min at time of listing
  - Candidates diagnosed with at least one of the following:
    - Hyperoxaluria
    - Atypical hemolytic uremic syndrome (HUS) from mutations in factor H or factor I
    - Familial non-neuropathic systemic amyloidosis
    - Methylmalonic aciduria
- Retransplantation. Usually due to primary non-function, rejection, recurrent disease and/or immunosuppression toxicity.

## Contraindications

- Systemic or uncontrolled infection including sepsis
- Reversible renal failure
- Significant uncorrectable life-limiting medical conditions
- Severe end-organ damage that would have an impact on patient survival
- Active untreated or untreatable malignancy
- Irreversible, severe brain damage
- Active substance use disorders
  While there is no evidence-based, optimal period of sobriety, an attempt at abstinence based on clinical status is expected. This would allow sufficient clinical improvement which may, in turn, avert the need for transplantation. *See Considerations for Substance Use Disorder section below for additional information.*
- Inactive alcohol and/or substance use (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication
- Recreational or medicinal use of marijuana is not a contraindication

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## Considerations for Substance Use Disorder

For patients experiencing catastrophic decompensation where a period of abstinence is not possible based on clinical status the transplant center must have an institutional protocol that requires, at a minimum:

- Appropriate patient and psychosocial support profile. Transplant center must have an institutional protocol to conduct psychosocial evaluation and proactively implement interventions to promote post-transplant success.
    - Presence of close supportive social network
    - Absence of severe coexisting behavioral health disorders that would negatively impact a treatment plan
    - Documentation on insight on the patients part of the genesis of this condition and how substance use contributed to the process
    - There must be documentation of a plan for post-transplantation rehabilitation and monitoring
    - The patient must agree to participate in such a program and commit to lifelong abstinence from addictive substances.
- Evaluation by a dedicated psychiatrist, psychologist, or an appropriate addiction specialist indicating high likelihood of success of post-transplant rehabilitation and abstinence
- Approval by a transplant selection committee that includes in addition to the regular members, a dedicated psychiatrist, psychologist, or an appropriate addiction specialist
- Any other substance use needs to be addressed
- Inactive alcohol and/or substance use (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication

## Special Considerations

*Additional consultation and/or evaluation may be indicated in these situations.*

Unless otherwise cited, the following recommendations are consistent with the 2020 Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guideline on the Evaluation and Management of Candidates for Kidney Transplantation (Chadban et al., 2020).

- Primary non-function or less than one year since the initial transplant may require additional evaluation to determine causative factors.
- Patients with a history of malignancy require an oncology evaluation to determine status of disease. Recommendations for suitability and timing of a solid organ transplant following successful treatment of malignancy may be found in Appendix B. The recommendations are based on Al-Adra et al. (2021).
- Social and psychiatric issues can have a significant impact on the outcomes of a transplant. It is expected that a psychosocial evaluation and/or psychiatry consultation is obtained as part of the standard transplant evaluation (Crone et al., 2010). The evaluation should address the following:
    - Overall functioning
    - Understanding of underlying illness and need for proposed treatment
    - History of adherence and compliance and barriers to compliance
    - Quality of relationships
    - Presence of a supportive caregiver
    - Social history, including educational level and employment history
    - Housing and living situation, including reliable transportation to attend medical visits
    - Socioeconomic status, including sufficient funding to pay for immunosuppressive medications post-transplant
    - Current and past history of alcohol and substance use

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  - Current and past psychiatric history, including baseline cognitive status and coping skills

- Patients with human immunodeficiency virus (HIV) infection must be on a highly active antiretroviral therapy (HAART) regimen and there must be documented evidence of sustained viral load suppression.
- BMI ≥ 35 kg/m$^2$. NOTE: There are few data to suggest which, if any, obese patients should be denied transplantation based on obesity per se (Kasiske et al., 2001).
  - Refer to requesting program patient selection criteria.
- Pediatric patients should have a normal history and physical, or if there is any indication of abnormal cardiac function, cardiology evaluation should be obtained.
- Adult patients with known heart disease including, but not limited to, heart failure, cardiomyopathy and coronary artery disease require cardiology consultation and completion of consultant's recommendations, if any.
- Gastrointestinal (GI) clearance may be indicated in patients with a history of complicated or active GI disorders.
- Significant, uncorrectable pulmonary disease. Pulmonary consultation and completion of consultant's recommendations if any is required.

# Kidney/Pancreas Transplantation

Medical necessity determinations must comply with the definitions and principles established in Rule 5160-1-01 - Ohio Administrative Code | Ohio Laws

## General information

- Simultaneous pancreas kidney (SPK) transplant is the definitive treatment of Type 1 diabetes combined with end-stage renal disease. Long-term graft function can lead to improvement in diabetes-related complications and, in patients younger than 50 years, can lead to improved overall survival. Pancreas after kidney (PAK) transplant and pancreas alone (PA) transplant do not result in similar improvements in patient survival, but with appropriate patient selection, they can improve quality of life by rendering the patient insulin-free (Dhanireddy, 2012; Boggi et al., 2021).
- Between 2020 and 2022, one-year pancreas graft survival remained stable at 90.8% for SPK, 87.5% for PTA, and 84.4% for PAK, with SPK also achieving 96.2% kidney graft survival. Mortality has steadily declined across all pancreas transplant types. From 2003 to 2022, one-year mortality fell to 1.3% (PAK), 4.2% (PTA), and 2.7% (SPK). Five-year and ten-year mortality also improved for all procedures over the same periods (OPTN, 2025).

## Indications

- SPK and PAK:
  - Qualifies for kidney transplant (see kidney criteria) **AND** the member is diabetic. The outcomes of combined kidney pancreas transplants in Type 2 diabetics are comparable to the outcomes in Type 1 diabetics (Redfield et al., 2016; Pham et al., 2021).
  - The criteria for covering a pancreas transplant alone are not applicable when a kidney is also being transplanted.

OSOTC patient selection criteria for pancreas transplantation may be found here: Review OSOTC Patient Selection Criteria | Indications & Contraindications

- Retransplantation is usually due to non-function of the grafted organ(s), chronic rejection, and chronic allograft pancreatitis.

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## Contraindications

- Systemic or uncontrolled infection including sepsis
- Reversible renal failure
- Significant cardiac disease (Stratta et a., 2015):
  - Non-correctable coronary artery disease
  - Ejection fraction (LVEF, EF) < 40%
- Significant uncorrectable life-limiting medical conditions
- Severe end-organ damage that would have an impact on patient survival
- Active untreated or untreatable malignancy
- Irreversible, severe brain damage
- Active substance use disorders
  While there is no evidence-based, optimal period of sobriety, an attempt at abstinence based on clinical status is expected. This would allow sufficient clinical improvement which may, in turn, avert the need for transplantation. *See Considerations for Substance Use Disorder section below for additional information.*
- Inactive alcohol and/or substance use (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication
- Recreational or medicinal use of marijuana is not a contraindication

## Considerations for Substance Use Disorder

For patients experiencing catastrophic decompensation where a period of abstinence is not possible based on clinical status the transplant center must have an institutional protocol that requires, at a minimum:

- Appropriate patient and psychosocial support profile. Transplant center must have an institutional protocol to conduct psychosocial evaluation and proactively implement interventions to promote post-transplant success.
  - Presence of close supportive social network
  - Absence of severe coexisting behavioral health disorders that would negatively impact a treatment plan
  - Documentation on insight on the patients part of the genesis of this condition and how substance use contributed to the process
  - There must be documentation of a plan for post-transplantation rehabilitation and monitoring
  - The patient must agree to participate in such a program and commit to lifelong abstinence from addictive substances.
- Evaluation by a dedicated psychiatrist, psychologist, or an appropriate addiction specialist indicating high likelihood of success of post-transplant rehabilitation and abstinence
- Approval by a transplant selection committee that includes in addition to the regular members, a dedicated psychiatrist, psychologist, or an appropriate addiction specialist
- Any other substance use needs to be addressed
- Inactive alcohol and/or substance use (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.) is not a contraindication

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## Special Considerations

*Additional consultation and/or evaluation may be indicated in these situations.*

- Social and psychiatric issues can have a significant impact on the outcomes of a transplant. It is expected that a psychosocial evaluation and/or psychiatry consultation is obtained as part of the standard transplant evaluation (Crone et al., 2010). The evaluation should address the following:
  - Overall functioning
  - Understanding of underlying illness and need for proposed treatment
  - History of adherence and compliance and barriers to compliance
  - Quality of relationships
  - Presence of a supportive caregiver
  - Social history, including educational level and employment history
  - Housing and living situation, including reliable transportation to attend medical visits
  - Socioeconomic status, including sufficient funding to pay for immunosuppressive medications post-transplant
  - Current and past history of alcohol and substance use
  - Current and past psychiatric history, including baseline cognitive status and coping skills
- Patients with a history of malignancy require an oncology evaluation to determine status of disease. Recommendations for suitability and timing of a solid organ transplant following successful treatment of malignancy may be found in Appendix B. The recommendations are based on Al-Adra et al. (2021).
- Patients with human immunodeficiency virus (HIV) infection must be on a highly active antiretroviral therapy (HAART) regimen and there must be documented evidence of sustained viral load suppression.
- BMI ≥ 35 $kg/m^2$:
  - All programs have patient selection criteria that may need to be reviewed.
- Pediatric patients should have a normal history and physical, or if there is any indication of abnormal cardiac function, cardiology evaluation should be obtained.
- Adult patients with known heart disease including, but not limited to, heart failure, cardiomyopathy and coronary artery disease require cardiology consultation and completion of consultant's recommendations, if any.
- Gastrointestinal (GI) clearance may be indicated in patients with a history of complicated or active GI disorders.
- Significant, uncorrectable pulmonary disease. Pulmonary consultation and completion of consultant's recommendations if any is required.

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# Appendix A: National Kidney Foundation Definition of Chronic Kidney Disease

- Kidney damage for ≥ 3 months, as defined by structural or functional abnormalities of the kidney, with or without decreased GFR, manifest by either:
  - Pathological abnormalities; or
  - Markers of kidney damage, including abnormalities in the composition of the blood or urine, or abnormalities in imaging tests
- GFR < 60 ml/min/1.73 $m^2$ for ≥ 3 months, with or without kidney damage

## Reference

What is the Criteria for CKD | National Kidney Foundation

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# **Appendix B:** Pretransplant Solid Organ Malignancy and Organ Transplant Candidacy: Recommendations for Time Interval to Transplant

The recommendations below are adapted from the consensus expert opinion statement of the American Society of Transplantation published in 2021.

| **Breast cancer** | | |
|---|---|---|
| **Risk/stage** | **Time interval to transplant** | **Additional considerations** |
| Low risk<br>DCIS<br>Stage I | No wait time necessary after completion of all standard treatments. | Endocrine therapy does not need to be completed prior to transplant. |
| Intermediate risk<br>Stage II | 1–2 years, no evidence of disease after completion of all standard treatments. | Mammogram prior to transplant recommended. |
| High risk<br>stage III | 3–5 years, no evidence of disease after completion of all standard treatments. | |
| Prohibitive risk<br>Stage V | Not a solid organ transplant candidate. | |
| **Colon cancer** | | |
| **Risk/stage** | **Time interval to transplant** | **Additional considerations** |
| Low risk<br>Stage I<br>(T1 or T2, N0, M0) | 1 year | Low-risk features:<br>• MSI without BRAF mutations |
| Low intermediate risk<br>Stage II<br>(T3, N0, M0) | 2 years, consider longer if high-risk features present. | High-risk features:<br>• Lymphovascular invasion (LVI) or perineural invasion (PVI)<br>• Mucinous, Signet or poorly differentiated histology<br>• Bowel obstruction<br>• Tumor perforation<br>• < 12 lymph nodes examined<br><br>Consider chemotherapy prior to transplant for high-risk stage II disease.<br>Patients with stage III disease should complete chemotherapy. |
| High intermediate risk<br>Stage II<br>(T4, N0, M0)<br><br>Stage III<br>(Any T, N+, M0) | 3 years, 5 years if high-risk features present. | |
| High risk<br>Stage IV<br>(Any T, Any N, M+) | 5 years, no evidence of disease. | Transplant not recommended prior to 5 years. |
| **Rectal cancer** | | |
| **Risk/stage** | **Time interval to transplant** | **Additional considerations** |

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| | | |
|---|---|---|
| Low risk<br>Stage I<br>(T1 or T2, N0, M0)<br>Full oncologic resection | 1 year, consider 2 years of high-risk features present. | Low-risk features:<br>• MSI without BRAF mutations<br>• Upper 1/3 rectum or rectosigmoid<br>High-risk features:<br>• LVI or PNI<br>• Mucinous, Signet or poorly differentiated histology<br>• Bowel obstruction<br>• Tumor perforation<br>• > 12 lymph nodes examined<br>• Lower 1/3 of rectum<br>• Incomplete mesorectal excision |
| Low intermediate risk<br>Stage I<br>(T1, N0, M0)<br>Local excision | 2 years | |
| High intermediate risk<br>Stage II<br>(T3 or T4, N0, M0)<br>Stage III<br>(Any T, N+, M0) | 3 years, 5 years if high-risk features present. | Patients with stage II and III disease should complete trimodality treatment (chemoradiotherapy, surgery and chemotherapy) unless elimination of one of these is deemed appropriate after multidisciplinary discussion. |
| High risk<br>Stage IV<br>(Any T, Any N, M+) | 5 years, no evidence of disease. | Transplant not recommended prior to 5 years. |
| **Prostate cancer** | | |
| **Risk/stage** | **Time interval to transplant** | **Additional considerations** |
| Very low risk<br>PSA < 10ng/ml<br>3 or fewer cores of Gleason 6 (grade group 1): no greater than 50% of individual core<br>(T1c-T2a) | None | Surveillance strongly recommended. |
| Low risk<br>PSA < 10ng/ml<br>Gleason 6 (not meeting very low risk criteria)<br>(T1c-T2a) | None | Surveillance strongly recommended. |
| Low-volume intermediate risk<br>One of the following criteria:<br>• PSA > 10ng/ml<br>• Gleason 7 (grade group 2 or 3)<br>• T2b | If surveillance, no wait time.<br>If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years < 10%, no wait time. | |
| High-volume intermediate risk, high risk or very high risk<br>PSA> 20ng/ml or high-volume Gleason 7 or Gleason 8-10, T3 | If treatment initiated, and nomogram predicts cancer-specific death over the next 15 years < 10%, no wait time. | |
| Metastatic castration-sensitive | If stable disease for 2 years with prolonged estimated life | |

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| | | |
|---|---|---|
| | expectancy, may consider transplant. | |
| Metastatic castration-resistant | Not a solid organ transplant candidate. | |

## Renal cell carcinoma

| Stage | Time interval to transplant | Additional considerations |
|---|---|---|
| T1a (≤ 4cm), N0, M0 | No wait time. | |
| T1b (> 4cm ≤ 7cm), N0, M | Fuhrman grade (FG) 1–2: no wait time.<br>FG 3–4: 1–2 years. | |
| T2 (7–10cm), N0, M0 | 2 years | |
| T3, N0, M0 | Minimum of 2 years, then reassess. | |
| T4, N0,M0 | Minimum of 2 years, then reassess. | |
| Any T, node positive, metastatic disease | Not a candidate (if solitary metastasis +resected, tumor board discussion on candidacy. | |
| Any T with sarcomatoid and/or rhabdoid histologic features | Not a solid organ transplant candidate. | |
| Collecting duct or medullary RCC | Not a solid organ transplant candidate. | |

## Bladder cancer

| Bladder cancer history | Time interval to transplant | Additional considerations |
|---|---|---|
| Non-muscle invasive bladder cancer (NMIBC) low risk<br>Solitary tumor ≤ 3cm, low grade, Ta, absence of carcinoma in situ (CIS) | 6 months | |
| Intermediate risk<br>Solitary tumor > 3cm, recurrence within 12 months with low-grade Ta tumor, multifocal low-grade Ta tumor, low-grade T1 tumor, or high-grade tumor < 3cm | 6 months | |
| High risk<br>Any CIS, high-grade Ta tumor > 3cm, high-grade T1 tumor, multifocal high-grade Ta tumor, any recurrent high-grade Ta tumor, variant histology, lymphovascular invasion, high-grade prostatic urethral involvement, recurrence after Bacillus Calmette-Guerin (BCG) intravesical therapy | 2 years | |
| Muscle invasive bladder cancer (MIBC), post-radical cystectomy | 2 years | |
| MIBC, post-chemoradiation | Not a solid organ transplant candidate. | |

## Gynecological cancer

| 5-year risk recurrence | Type/stage | Time interval to transplant |
|---|---|---|
| Low risk<br>< 5% risk of recurrence | Stage IA/IB, grade 1–2 endometrial cancer. | No waiting period after completion of primary treatment. |

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| | | |
|---|---|---|
| | Stage IA/IB/IC grade 1–2 epithelial ovarian cancer.<br><br>Stage IA1, IA2 squamous/adenocarcinoma of cervix. | |
| Intermediate risk<br>5%–15% risk of recurrence | Stage I/II endometrial cancer + risk factors (older age, lymph-vascular space invasion, grade 2 or 3 endometroid, deeply invasive tumor). | 2–3 years after completion of treatment. |
| High risk<br>> 30% risk of recurrence | Serous, clear cell, or carcinosarcoma of uterus (all stages).<br>Stage III grade 1–3 endometrioid cancer of uterus.<br>Stage II/III epithelial ovarian cancer.<br>Stage II/III squamous cell/adenocarcinoma cervical cancer. | 5 years after completion of treatment. |
| Very high risk<br>> 80% chance of recurrence | Stage IV endometrial cancer (all grades).<br>Recurrent or metastatic endometrial cancer.<br>Stage IV epithelial ovarian cancer (any grade).<br>Stage IV squamous cell/adenocarcinoma of cervix.<br>Metastatic or recurrent cervical cancer. | Not a solid organ transplant candidate. |
| **Lung cancer** | | |
| **Stage, tumor, and node** | **Time interval to transplant** | **Workup pretransplant** |
| I, T1a, N0 | ≥ 3 years | PET-CT; consider biopsy post-stereotactic body radiation therapy (SBRT). |
| I, T1b, N0 | ≥ 3 years | PET-CT; consider biopsy post-SBRT. |
| I, T1c, N0 | 3-5 years | PET-CT; consider biopsy post-SBRT. |
| IB, T2a, N0 | 5 years | PET-CT |
| IIA, T2b, N0 | 5 years | PET-CT |
| IIB, T3, N0 | 5 years | PET-CT |
| IIIA | 5 years | PET-CT |
| IIIB | Not a solid organ transplant candidate. | N/A |
| IIIC | Not a solid organ transplant candidate. | N/A |
| IVA | Not a solid organ transplant candidate. | N/A |

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| | | |
|---|---|---|
| IVB | Not a solid organ transplant candidate. | N/A |

## Reference

Al-Adra DP, Hammel L, Roberts J, et al. Pretransplant solid organ malignancy and organ transplant candidacy: A consensus expert opinion statement. Am J Transplant. 2021 Feb;21(2):460-474. doi: 10.1111/ajt.16318. Epub 2020 Oct 23. PMID: 32969590; PMCID: PM

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# Review and Approval History

| Version | Description |
|---|---|
| **1.0** | **07/19/2012:** New clinical guideline. |
| **2.0** | **10/10/2013:** Annual review. |
| **3.0** | **08/07/2014:** Annual review. |
| **4.0** | **08/25/2015:** Annual review. |
| **5.0** | **08/16/2016:** Annual review. |
| **6.0** | **09/07/2017:** Annual review. |
| **7.0** | **08/18/2018**: Annual review of abdominal organ transplant content. |
| **7.0** | **12/05/2018:** Annual review of thoracic organ transplant content. |
| **8.0** | **8/7/2019:** Annual review of abdominal solid organ content. Version effective date: 12/1/2019. |
| **9.0** | **1/15/2020:** Annual review of thoracic solid organ content. Version effective date: 4/1/2020. |
| **9.0** | **7/29/2020:** Annual review of abdominal solid organ content. Version effective date: 10/1/20. |
| **10.0** | **2/10/2021:** Annual review of thoracic solid organ content. Version effective date: 4/1/21. |
| **10.0** | **7/14/2021:** Annual review of abdominal solid organ content. Version effective date: 9/10/21. |
| **11.0** | **2/23/2022:** Annual review of thoracic solid organ. Lung transplant indications revised for clarity. SARS-CoV2 Vaccination Statement added. Version effective date: 5/9/22. |
| **11.0** | **9/27/2022:** Annual review of abdominal solid organ content. Added hilar and perihilar cholangiocarcinoma to liver transplant indications. Version effective date: 11/3/22. |
| **12.0** | **3/1/2023:** Annual review of thoracic solid organ content. Heart liver transplant and cardiac amyloidosis indications added. |
| **12.0** | **9/26/2023:** Annual review of the abdominal solid organ content. Medical necessity criteria added for Donislecel (Lantidra). |
| **12.0** | **11/17/2023:** Approved by Pharmacy &Therapeutics (P&T) Committee. |
| **12.0** | **12/7/2023:** Approved by the Medical Technology Assessment Committee (MTAC). |
| **12.0** | **12/13/2023:** Approved by the Medicare Advantage Policy and Technology Assessment Committee (MAP TAC). |
| **13.0** | **6/26/2024:** Annual review of the thoracic solid organ content with the Optum Thoracic Solid Organ Transplantation Expert Panel. |
| **13.0** | **8/09/2024:** Annual review of the thoracic solid organ content. Approved by Optum Clinical Guideline Advisory Committee. |
| **13.0** | **9/05/2024:** Annual review of the thoracic solid organ content. Approved by Medical Technology Assessment Committee (MTAC). |
| **13.0** | **9/11/2024:** Annual review of the abdominal solid organ content with the Optum Abdominal Solid Organ Transplantation Expert Panel. |

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| **13.0** | **10/09/2024:** Annual review of the abdominal solid organ content. Approved by Optum Clinical Guideline Advisory Committee. |
| **13.0** | **11/07/2024:** Annual review of the abdominal solid organ content. Approved by Medical Technology Assessment Committee (MTAC). |
| **14.0** | **10/08/2025:** Annual review of the entire guideline content. Approved by Optum Clinical Guideline Advisory Committee. |
| **14.0** | **11/06/2025:** Approved by Medical Technology Assessment Committee. |
| **14.0** | **12/10/2025:** Approved by Medicare Advantage Policy and Technology Assessment Committee. |
| **14.0** | **02/05/2026**: Interim update: Scope of guideline limited to kidney transplantation. |
| **15.0** | **08/05/2026:** Annual review of the thoracic solid organ content with the Optum Thoracic Solid Organ Transplantation Expert Panel. |
| **15.0** | **08/26/2026:** Annual review of the abdominal solid organ content with the Optum Abdominal Solid Organ Transplantation Expert Panel. |
| **15.0** | **09/14/2026:** Annual review.<br>Updated the following:<br>• Adult liver transplantation contraindications<br>• Intestinal transplantation indications<br>• Multivisceral transplantation indications<br>• Pediatric lung transplantation indications<br>Approved by Optum Clinical Guideline Advisory Committee. |
| **15.0** | **10/01/2026:** Annual review.<br>Updated the following:<br>• Adult liver transplantation contraindications<br>• Intestinal transplantation indications<br>• Multivisceral transplantation indications<br>• Pediatric lung transplantation indications<br>Approved by Medical Technology Assessment Committee. |
| **15.0** | **10/14/2026:** Annual review.<br>Updated the following:<br>• Adult liver transplantation contraindications<br>• Intestinal transplantation indications<br>• Multivisceral transplantation indications<br>• Pediatric lung transplantation indications<br>Approved by Medicare Advantage Policy and Technology Assessment Committee. |

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