## Addendum to Technical Guidance and Instructions for 2025 Benefits Proposals

### Introduction

This is an addendum to Carrier Letter 2024-06, Technical Guidance and Instructions for 2025 Benefit Proposals.

The following information focuses on Summary of Benefits and Coverage and Organ/Tissue Transplant guidance. There are no new requirements.

FEHB Carriers will submit Appendix XIII as part of their proposal. PSHB Carriers must use <u>Carrier Connect</u> to submit all benefit and rate proposal materials. If you have questions, please contact your Health Insurance Specialist.

## **Applicable to All Carriers**

#### Summary of Benefits and Coverage

All Carriers must provide a Summary of Benefits and Coverage (SBC) for each plan based on standards developed by the Departments of Labor, Health and Human Services, and the Treasury.

#### Appendix XIII: 2025 Organ/Tissue Transplants and Diagnoses

The information required in the following appendix must be completed and returned to OPM as part of your Plan Year 2025 proposal. FEHB Carriers will submit these worksheet appendices as part of their proposal. If you have questions, please contact your Health Insurance Specialist.

Technology and clinical advancements are continually evolving. FEHB and PSHB Carriers are encouraged to provide coverage during the contract year for transplant services recommended under clinical trials and transplant services that transition from experimental/investigational. These types of transplants may transition from experimental/investigational and become consistent with standards of good medical practice in the U.S. for the diagnosed condition. As in past years, we are providing guidance on organ/tissue transplants for 2025. When you determine that a transplant service is no longer experimental, but is medically necessary, you may begin providing benefits coverage at that time. FEHB and PSHB Carriers are not obligated to wait for the next contract year before they begin providing such benefits.

- Section 1 OPM's required list of covered organ/tissue transplants.
- Section 2 OPM's recommended coverage of transplants under Clinical Trials. All Carriers are to complete and return the worksheet below.
- Section 3 OPM's recommended list of covered rare organ/tissue transplants. All Carriers are to complete and return the worksheet below.

If you have further questions, please contact your Health Insurance Specialist.

#### Section 1: Required Coverage of Organ/Tissue Transplants

#### I. Solid Organ and Tissues Transplants: Subject to Medical Necessity

- Cornea
- Heart
- Heart Lung
- Kidney
- Kidney Pancreas
- Liver
- Pancreas
- Autologous pancreas islet cell transplant (as an adjunct to total or near total pancreatectomy) only for patients with chronic pancreatitis
- Intestinal transplants (small intestine with the liver) or (small intestine with multiple organs such as the liver, stomach, and pancreas) or isolated small intestine
- Lung: Single/bilateral/lobar

#### II. Hematopoietic Stem Cell Transplant (HSCT)

Since the 2024 Plan Year, OPM has aligned the requirements for hematopoietic stem cell transplant (HSCT) coverage with those of the American Society for Transplantation and Cellular Therapy (ASTCT) as published in 2020<sup>1</sup>. ASTCT is the professional society for hematopoietic stem cell transplantation in the United States. Authors included both adult and pediatric clinicians, as well as payer representatives. ASTCT plans to update this publication on a 3–5-year basis. It is important to note that requirements for FEHB and PSHB coverage taken from this manuscript are

<sup>&</sup>lt;sup>1</sup> Kanate AS, Majhail NS, Savani BN, et al. Indications for Hematopoietic Cell Transplantation and Immune Effector Cell Therapy: Guidelines from the American Society for Transplantation and Cellular Therapy. Biol Blood Marrow Transplant. 2020. 26 (7) 1247-1256. DOI: <u>https://doi.org/10.1016/j.bbmt.2020.03.002</u>.

for HSCT only, and no recommendations are made regarding immune effector cell therapy. Since both OPM's previous guidance and ASTCT's manuscript reflect current standards of care and evidence, OPM believes that both documents align, without meaningful differences between them.

**Table 1** from the <u>manuscript</u> defines the levels of evidence supporting various indications. OPM recommends that FEHB and PSHB Carriers cover Standard of Care (S), Standard of Care, clinical evidence available (C), and Standard of Care, rare indication (R). Developmental(D) is also recommended for coverage within the context of a clinical trial, and Not generally recommended (N) is not recommended for coverage. **Table 4** from the <u>manuscript</u> lists pediatric indications for HSCT and **Table 5** from the <u>manuscript</u> lists adult (> 18 years) indications for HSCT.

Plans must clearly indicate coverage for Blood or Marrow Stem Cell Transplants in their plan brochures under required transplant coverage. Plans may link to the coverage criteria outlined in the manuscript.

# Note: PSHB Carriers must use Carrier Connect to submit proposal materials.

#### Section 2: Recommended for Coverage: Transplants under Clinical Trials

Please return this worksheet with your proposal.

Blood or Marrow Stem Cell Transplants	Does your plan cover this transplant for 2025? Yes/No
Early stage (indolent or non-advanced) small cell lymphocytic lymphoma	
Multiple myeloma	
Multiple sclerosis	
Sickle Cell	
Beta Thalassemia Major	
Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)	

Blood or Marrow Stem Cell Transplants	Does your plan cover this transplant for 2025? Yes/No
Acute lymphocytic or non-lymphocytic (i.e., myelogenous) leukemia	
Hodgkin's lymphoma	
Non-Hodgkin's lymphoma	
Breast cancer	
Chronic lymphocytic leukemia	
Chronic myelogenous leukemia	
Colon cancer	
Chronic lymphocytic lymphoma/small lymphocytic lymphoma (CLL/SLL) relapsed/refractory disease	
Early stage (indolent or non-advanced) small cell lymphocytic lymphoma	
Multiple Myeloma	
Multiple Sclerosis	
Myeloproliferative Disorders	
Myelodysplasia/Myelodysplastic Syndromes	
Non-small cell lung cancer	
Ovarian cancer	
Prostate cancer	
Renal cell carcinoma	
Sarcomas	
Sickle Cell disease	

Blood or Marrow Stem Cell Transplants	Does your plan cover this transplant for 2025? Yes/No
Chronic myelogenous leukemia	
Chronic lymphocytic lymphoma/small lymphocytic lymphoma (CLL/SLL)	
Early stage (indolent or non-advanced) small cell lymphocytic lymphoma	
Small cell lung cancer	
Multiple sclerosis	
Systemic lupus erythematosus	
Systemic sclerosis	
Scleroderma	
Scleroderma-SSc (severe, progressive)	

#### Section 3: Recommended for Coverage: Rare Organ/Tissue Transplants

Please return the worksheet below with your proposal.

Solid Organ Transplants	Does your plan cover this transplant for 2025? Yes/No
Allogeneic islet transplantation	
Blood or Marrow Stem Cell Transplants	
Allogeneic transplants for:	
Advanced neuroblastoma	
Infantile malignant osteopetrosis	

Solid Organ Transplants	Does your plan cover this transplant for 2025? Yes/No
Kostmann's syndrome	
Leukocyte adhesion deficiencies	
Mucolipidosis (e.g., Gaucher's disease, metachromatic leukodystrophy, adrenoleukodystrophy)	
Mucopolysaccharidosis (e.g., Hunter's syndrome, Hurler's syndrome, Sanfilippo's syndrome, Maroteaux Lamy syndrome variants)	
Myeloproliferative disorders	
Sickle cell anemia	
X-linked lymphoproliferative syndrome	
Ependymoblastoma	
Ewing's sarcoma	
Medulloblastoma	
Pineoblastoma	
Waldenstrom's macroglobulinemia	