2023 Blue Cross and Blue Shield Service Benefit Plan - FEP Blue Focus Section 5(b). Surgical and Anesthesia Services Provided by Physicians and Other Healthcare Professionals Organ/Tissue Transplants

Organ/Tissue Transplants

Prior approval requirements:

For the transplants listed below, you must obtain prior approval (see pages <u>19-22</u>) from the Local Plan, for the procedure and precertification (see page <u>19</u>) for the facility admission. Prior approval is not required for kidney transplants or for transplants of corneal tissue. Additional benefit requirements apply for the coverage of certain transplants, see pages <u>66-67</u>.

- Blood or marrow stem cell transplant procedures Note: See pages <u>64-65</u> for **additional requirements** that apply to blood or marrow stem cell transplants that are covered only as part of a **clinical trial**.
- Autologous pancreas islet cell transplant
- Heart-lung transplant
- Heart transplant
- Implantation of an artificial heart as a bridge to transplant or destination therapy
- Intestinal transplants (small intestine with or without other organs)
- Liver transplant
- Lung (single, double, or lobar) transplant
- Pancreas transplant
- Combination liver-kidney transplant
- Combination pancreas-kidney transplant

Covered organ/tissue transplants are listed on page <u>66</u>. Benefits are subject to medical necessity and experimental/investigational review, and to the prior approval requirements shown above.

In addition, benefits are only available for some transplants (and covered related services) when performed in a Blue Distinction Center or Medicare-Approved Transplant Program. Please see pages

<u>65-66</u> for more information on the benefits available for the services below. Benefits for implantation of an artificial heart as a bridge to transplant or destination therapy are only available when the facility is designated as a Blue Distinction Center for heart transplants.

Must be performed in a Blue Distinction Center for Transplant:

- Blood or marrow stem cell transplants
- Heart transplants
- Liver transplants
- Adult single, double or lobar lung transplants
- Adult combination liver-kidney transplants

Must be performed in a Medicare-Approved Transplant Program:

- Heart-lung transplants
- Kidney
- Intestinal
- Adult pancreas transplants
- Pediatric lung transplants
- Adult combination pancreas-kidney transplants

Must be performed in a Preferred hospital by a Preferred provider:

- Autologous pancreas islet cell transplants
- Corneal tissue transplants
- Pediatric pancreas transplants
- Pediatric combination liver-kidney transplants
- Pediatric combination pancreas-kidney transplants

Note: Refer to pages <u>19-22</u> for information about precertification of inpatient care.

Blood or marrow stem cell transplants are covered as shown below and on pages <u>64-65</u>. Benefits are limited to the stages of the diagnoses listed.

Physicians consider many features to determine how diseases will respond to different types of treatments. Some of the features measured are the presence or absence of normal and abnormal chromosomes, the extension of the disease throughout the body, and how fast the tumor cells grow. By analyzing these and other characteristics, physicians can determine which diseases may respond to treatment without transplant and which diseases may respond to transplant. For the diagnoses listed on the following pages, the medical necessity limitation is considered satisfied if the patient meets the staging description.

Notes:

- Coverage for the blood or marrow stem cell transplants described below and on the top of page 65 includes benefits for those transplants performed in an approved clinical trial to treat any of the conditions listed when prior approval is obtained. Refer to the bottom of page 64 and the top of page 65 for information about blood or marrow stem cell transplants covered only in clinical trials and the additional requirements that apply.
- See page <u>122</u> for our coverage of other costs associated with clinical trials.

The following transplants are only covered for the diagnosis indicated for the transplant procedure.

Benefits for Allogeneic blood or marrow stem cell transplants are only available for the diagnoses as indicated below:

- Acute lymphocytic or non-lymphocytic (i.e., myelogenous) leukemia
- Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) with poor response to therapy, short time to progression, transformed disease, or high risk disease
- Chronic myelogenous leukemia
- Hemoglobinopathy (i.e., sickle cell anemia, thalassemia major)
- High-risk neuroblastoma
- Hodgkin's lymphoma
- Infantile malignant osteopetrosis
- Inherited metabolic disorders (e.g., Gaucher's disease, metachromatic leukodystrophy, adrenoleukodystrophy, Hurler's syndrome and Maroteaux-Lamy syndrome variants)
- Marrow failure (i.e., severe or very severe aplastic anemia, Fanconi's anemia, paroxysmal nocturnal hemoglobinuria (PNH), pure red cell aplasia, congenital thrombocytopenia)
- MDS/MPN (e.g., chronic myelomonocytic leukemia (CMML))
- Myelodysplasia/myelodysplastic syndromes (MDS)
- Myeloproliferative neoplasms (MPN) (e.g., polycythemia vera, essential thrombocythemia, primary myelofibrosis)
- Non-Hodgkin's lymphoma (e.g., Waldenstrom's macroglobulinemia, B-cell lymphoma, Burkitt lymphoma)

- Paroxysmal Nocturnal Hemoglobinuria
- Phagocytic/Hemophagocytic deficiency diseases (e.g., Wiskott-Aldrich syndrome)
- Plasma cell disorders (e.g., multiple myeloma, amyloidosis, polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes (POEMS) syndrome)
- Primary immunodeficiencies (e.g., severe combined immunodeficiency, Wiskott-Aldrich syndrome, hemophagocytic lymphohistiocytosis, X-linked lymphoproliferative syndrome, Kostmann's syndrome, leukocyte adhesion deficiencies)
- Severe combined immunodeficiency
- Severe or very severe aplastic anemia
- Sickle cell anemia
- X-linked lymphoproliferative syndrome

Notes:

- See page <u>62</u> for the prior approval and facility transplant program requirements that apply to blood or marrow stem cell transplants.
- Refer to pages <u>64-65</u> for information about blood or marrow stem cell transplants covered only in clinical trials.

Benefits for Autologous blood or marrow stem cell transplants are only available for the diagnoses as indicated below:

- Acute lymphocytic or non-lymphocytic (i.e., myelogenous) leukemia
- Central nervous system (CNS) embryonal tumors (e.g., atypical teratoid/rhabdoid tumor, primitive neuroectodermal tumors (PNETs), medulloblastoma, pineoblastoma, ependymoblastoma)
- Ewing's sarcoma
- Germ cell tumors (e.g., testicular germ cell tumors)
- High-risk neuroblastoma

- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma (e.g., Waldenstrom's macroglobulinemia, B-cell lymphoma, Burkitt lymphoma)
- Plasma cell disorders (e.g., multiple myeloma, amyloidosis, polyneuropathy, organomegaly, endocrinopathy, monoclonal gammopathy, and skin changes (POEMS) syndrome)
- Scleroderma

Notes:

- See page <u>62</u> for the prior approval and facility transplant program requirements that apply to blood or marrow stem cell transplants.
- See below and page <u>65</u> for information about **blood or marrow stem cell transplants covered only in clinical trials**.

Clinical Trials:

Clinical trials are research studies in which physicians and other researchers work to find ways to improve care. Each study tries to answer scientific questions and to find better ways to prevent, diagnose, or treat patients. A clinical trial has possible benefits as well as risks. Each trial has a protocol which explains the purpose of the trial, how the trial will be performed, who may participate in the trial, and the beginning and end points of the trial. Information regarding clinical trials is available at www.cancer.gov/about-cancer/treatment/clinical-trials.

Even though we may state benefits are available for a specific type of clinical trial, you may not be eligible for inclusion in these trials or there may not be any trials available in a Blue Distinction Center for Transplants to treat your condition at the time you seek to be included in a clinical trial. If your physician has recommended you participate in a clinical trial, we encourage you to contact the Case Management Department at your Local Plan for assistance.

Transplants that may be eligible for clinical trials:

Benefits for Blood or marrow stem cell transplants are available for the diagnoses below, **only** when performed as part of a **clinical trial** that meets the transplant program prior approval criteria described on page <u>62</u> and the **requirements** listed below, when a clinical trial for the diagnosis is available in a Blue Distinction Center; and you meet the criteria for inclusion in the clinical trial:

- Allogeneic blood or marrow stem cell transplants for:
 - Breast cancer

- Colon cancer
- Epidermolysis bullosa
- Glial tumors (e.g., anaplastic astrocytoma, choroid plexus tumors, ependymoma, glioblastoma multiforme)
- Ovarian cancer
- Prostate cancer
- Renal cell carcinoma
- Retinoblastoma
- Rhabdomyosarcoma
- Sarcoma
- Wilm's tumor
- Allogeneic blood or marrow stem cell transplants or autologous blood or marrow stem cell transplants for:
 - Autoimmune disease (limited to: multiple sclerosis, scleroderma, systemic lupus erythematosus and chronic inflammatory demyelinating polyneuropathy)
- Autologous blood or marrow stem cell transplants for:
 - Autoimmune disease (limited to: multiple sclerosis, systemic lupus erythematosus and chronic inflammatory demyelinating polyneuropathy)
- Autologous blood or marrow stem cell transplants for:
 - Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)
 - Chronic myelogenous leukemia
 - Glial tumors (e.g., anaplastic astrocytoma, choroid plexus tumors, ependymoma, glioblastoma multiforme)
 - Retinoblastoma
 - o Rhabdomyosarcoma
 - o Wilm's tumor and other childhood kidney cancers

Note: A transplant clinical trial may not be available for your condition. If you or your provider are considering a clinical trial, please contact us at the phone number on the back of your ID card for assistance in determining if a covered clinical trial is available in a covered facility.

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If a non-randomized clinical trial for a blood or marrow stem cell transplant listed above meeting the **requirements** shown on pages <u>64-65</u> is not available in a covered facility near you, we will arrange for the transplant to be provided at an approved transplant program, if a clinical trial is available and you meet the inclusion criteria to participate in the clinical trial.

Benefits for Blood or marrow stem cell transplants are only available for the diagnoses as indicated above only when performed at a Blue Distinction Center for Transplants (see page <u>17</u>) as part of a clinical trial that meets the requirements listed below:

- You must contact us at the customer service phone number listed on the back of your ID card to obtain prior approval (see pages <u>19-22</u>); and
- The patient must be properly and lawfully registered in the clinical trial, meeting all the eligibility requirements of the trial; and
- For the transplant procedures listed above, the clinical trial must be reviewed and approved by the Institutional Review Board for the Blue Distinction Center for Transplant program where the procedure is to be performed.

See page <u>122</u> for our coverage of other costs associated with clinical trials.

Benefit Description

Organ/Tissue Transplants

The following transplants **must** be performed at a **Blue Distinction Centers for Transplants** (see page <u>17</u> for more information):

- Blood or marrow stem cell transplants (adult and pediatric) listed on pages 63-64
- Heart transplant (adult and pediatric)
 - Implantation of an artificial heart as a bridge to transplant or destination therapy (when performed in a Blue Distinction Center for Heart Transplants)
- Liver transplant (adult and pediatric)
- Lung:
 - $\circ\,$ For members with end-stage cystic fibrosis, benefits for lung transplantation are limited to double lung transplants
- Combination liver-kidney transplant
- Single, double, or lobar lung transplant (adult)

Note: For covered related transplant services, see pages <u>66</u> and <u>67</u>.

You Pay

When performed in a Blue Distinction Centers for Transplants: 30% of the Plan allowance (deductible applies)

All other providers (Participating/Non-participating): You pay all charges

Note: Your provider will document the place of service when filing your claim for the procedure(s). Please contact the provider if you have any questions about the place of the service.

Benefit Description

The following transplants are <u>not</u> available in a Blue Distinction Centers for Transplants[®] and **must** be performed at a Preferred facility with a Medicare-Approved transplant program, if one is available (see below):

- Autologous pancreas islet cell transplant (as an adjunct to total or near total pancreatectomy) only for patients with chronic pancreatitis
- Corneal tissue transplant
- Heart-lung transplant
- Intestinal transplants (small intestine) and the small intestine with the liver or small intestine with multiple organs such as the liver, stomach, and pancreas
- Kidney transplant
- Pancreas transplant
- Combination liver-kidney transplant (pediatric)
- Combination pancreas-kidney transplant
- Single, double, or lobar lung transplant (pediatric)

Notes:

• **Organ transplants** that are not available in a Blue Distinction Center for Transplants must be performed in a facility with a Medicare-Approved Transplant Program for the type of transplant anticipated. Transplants involving more than one organ must be performed in a facility that offers a Medicare-Approved Transplant Program for each organ transplanted. Contact your

local Plan for Medicare's approved transplant programs.

• If Medicare does not offer an approved program for a certain type of organ transplant procedure, this requirement does not apply and you may use any Preferred facility that performs the procedure. If Medicare offers an approved program for an anticipated organ transplant, but your facility is not approved by Medicare for the procedure, please contact your Local Plan at the customer service phone number appearing on the back of your ID card.

You Pay

Preferred: 30% of the Plan allowance (deductible applies)

Non-preferred (Participating/Non-participating): You pay all charges

Note: Your provider will document the place of service when filing your claim for the procedure(s). Please contact the provider if you have any questions about the place of the service.

Benefit Description

Related transplant services:

- Extraction or reinfusion of blood or marrow stem cells as part of a covered allogeneic or autologous transplant
- Harvesting, immediate preservation, and storage of stem cells when the autologous blood or marrow stem cell transplant has been scheduled or is anticipated to be scheduled within an appropriate time frame for patients diagnosed at the time of harvesting with one of the conditions listed on pages <u>63-65</u>

Note: Benefits are available for charges related to fees for storage of harvested autologous blood or marrow stem cells related to a covered autologous stem cell transplant that has been scheduled or is anticipated to be scheduled within an appropriate time frame. No benefits are available for any charges related to fees for long-term storage of stem cells.

- Collection, processing, storage and distribution of cord blood only when provided as part of a blood or marrow stem cell transplant scheduled or anticipated to be scheduled within an appropriate time frame for patients diagnosed with one of the conditions listed on pages <u>63-65</u>
- Covered medical and hospital expenses of the donor, when we cover the recipient
- Covered services or supplies provided to the recipient
- Donor screening tests for non-full sibling (such as unrelated) potential donors, for any full sibling potential donors, and for the actual donor used for transplant

Note: See Section 5(a) for coverage for related services, such as chemotherapy and/or radiation therapy and drugs administered to stimulate or mobilize stem cells for covered transplant procedures.

You Pay

Preferred: 30% of the Plan allowance (deductible applies)

Non-preferred (Participating/Non-participating): You pay all charges

Benefit Description

Travel benefits:

Members who receive covered care at a **Blue Distinction Center for Transplants** for one of the transplants listed on page <u>65</u> can be reimbursed for incurred travel costs related to the transplant, subject to the criteria and limitations described here.

You must obtain prior approval for travel benefits (see page 22).

You Pay

We reimburse costs for transportation (air, rail, bus, and/or taxi) and lodging if you live 50 miles or more from the facility, up to a maximum of \$5,000 per transplant for the member and companions. Reimbursement is subject to IRS regulations.

Benefit Description

Not covered:

- Any transplant not listed as covered and transplants for any diagnosis not listed as covered
- Transplants performed in a facility other than the type of facility required for the particular transplant (see page <u>66</u> regarding transplants that must be performed in a Blue Distinction Center for Transplants and page <u>66</u> for transplants that must be performed in a Medicare-Approved Transplant Program)
- Donor screening tests and donor search expenses, including associated travel expenses, except as defined above
- Implants of artificial organs, including those implanted as a bridge to transplant and/or as destination therapy, other than medically necessary implantation of an artificial heart as described on page <u>66</u>
- Implantation of an artificial heart in a facility not designated as a Blue Distinction Center for Heart Transplant

- Allogeneic pancreas islet cell transplantation
- Travel costs related to covered transplants performed at facilities other than Blue Distinction Centers for Transplants; travel costs incurred when prior approval has not been obtained; travel costs outside those allowed by IRS regulations, such as food-related expenses

You Pay All charges