Medical and Behavioral Health Policy Activity

Policies Effective: May 6, 2024. Notification Posted: March 1, 2024.

Policies Developed

- **Implantable Bone Conduction and Bone-Anchored Hearing Aids, IV-178**

I. Review for Conductive or Mixed Hearing Loss

Unilateral or bilateral, fully or partially implantable bone-anchored hearing aid(s) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when the following criteria are met:

- Age 5 years or older; **AND**
- Diagnosis of conductive or mixed hearing loss; **AND**
- Anatomical contraindication to an air-conduction hearing aid; **AND**
- A pure-tone average bone-conduction threshold measured at 0.5, 1, 2, and 3 kHz of ≥ ONE of the following:
  - 45 decibels for OBC and BP100 devices; OR
  - 55 decibels for Intenso device; OR
  - 65 decibels for Cordelle II device; OR
  - An average decibel threshold consistent with the device-specific FDA approval;

  AND
- **ONE** of the following:
  - Bone-anchored hearing aid will be inserted via unilateral implantation; OR
  - Bone-anchored hearings aid will be inserted via bilateral implantation, including BOTH of the following:
    - Symmetrically conductive or mixed hearing loss; AND
    - Difference between left and right-side bone-conduction threshold including ONE of the following:
      - < 10 decibels on average measured at 0.5, 1, 2, and 3 kHz; OR
      - < 15 decibels at individual frequencies; OR
      - < 10 decibels on average measured at 4 kHz for OBC and Pronto Pro device.

II. Review for Single-Sided Sensorineural Hearing Loss

A fully or partially implantable bone-conduction hearing aid may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 5 years or older; **AND**
- Single-sided sensorineural deafness in one ear with normal hearing in the other ear; **AND**
- Used as an alternative to an air-conduction contralateral routing or signal hearing aid in single-sided sensorineural hearing loss; **AND**
- Pure-tone average air-conduction threshold of the normal ear is > 20 decibels measured at 0.5, 1, and 3 kHz**.**

III. Experimental/ Investigative Uses

All other uses of unilateral or bilateral, fully or partially implantable bone-anchored hearing aid(s), including use in individuals with bilateral sensorineural hearing loss, are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Motixafortide (Aphexda), II-292**

I. Initial Review for Motixafortide (Aphexda™)

Motixafortide may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 18 years or older; **AND**
- Diagnosis of multiple myeloma; **AND**
- Used to mobilize hematopoietic stem cells for collection prior to autologous transplantation; **AND**
- Used in combination with subcutaneous or intravenous filgrastim or biosimilar filgrastim; **AND**
- Prescribed by, or in consultation with, an oncologist or hematologist; **AND**
- No FDA labeled contraindications to motixafortide (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

II. Renewal Review for Motixafortide (Aphexda™)

Use of motixafortide beyond two doses or after completion of stem cell harvest/apheresis is considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

III. Experimental/Investigative Uses

All other uses of motixafortide, including but not limited to use as a mobilizing agent for an allogeneic stem cell donor, are considered **EXPERIMENTAL/ INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Motixafortide	History of serious hypersensitivity reaction to motixafortide.

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Mobilization of hematopoietic stem cells for autologous transplant in multiple myeloma	Administer based on actual body weight: 1.25 mg/kg via subcutaneous injection 10 to 14 hours prior to initiation of the first apheresis. A second dose can be administered 10 to 14 hours before a third apheresis, if necessary.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

1. Clinical notes describing the diagnosis and clinical features of the diagnosis.
2. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments.

3. The dose being requested, including the patient's weight if the diagnosis requires weight-based dosing. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose MUST be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Policies Revised

- **Facet Arthroplasty, IV-110**
  Facet arthroplasty is considered **EXPERIMENTAL/ INVESTIGATIVE** for all indications, including but not limited to facet arthrosis, spinal stenosis, and spondylolisthesis, due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Genetic Testing for Hereditary Breast and/or Ovarian Cancer, VI-16**
  NOTES:
  - This policy only addresses genetic testing for breast and/or ovarian cancer.
  - Please refer to policy VI-49: Expanded Molecular Panel Testing of Cancers to Identify Targeted Therapies, for pharmacogenetic testing to aid in identifying targeted therapies for breast or ovarian cancers.
  - Please refer to policy VI-56: Genetic Cancer Susceptibility Panels, for multi-gene panel testing for other cancers.

  I. <u>Genetic Counseling</u>

  Genetic testing for hereditary breast and/or ovarian cancer may be considered **MEDICALLY NECESSARY and APPROPRIATE** when ALL of the following criteria for genetic counseling are met along with criteria in sections II, IV, or V below:

  - A recommendation for testing is confirmed by **ONE** of the following:
    - A physician who is certified by the American Board of Medical Genetics and Genomics or has active candidate status for certification who has no financial relationship with the testing laboratory*;
    - An American Board of Medical Genetics and Genomics or American Board of Genetic Counseling certified or certification eligible Genetic Counselor who has no financial relationship with the testing laboratory*;
    - A nurse credentialed as either a Genetic Clinical Nurse (GCN) or an Advanced Practice Nurse in Genetics (APNG) by either the Genetic Nursing Credentialing Commission (GNCC) or the American Nurses Credentialing Center (ANCC) who has no financial relationship with the testing laboratory*;
    - An oncologist or a surgical oncologist who has no financial relationship with the testing laboratory*;

    AND
  - Content of counseling includes BOTH of the following:
    - Evaluation of a 3-generation pedigree; and
    - Discussion of ALL of the following with the individual who is considering testing:
      - When clinically appropriate, options for surveillance and risk reduction (e.g., lifestyle, chemoprevention, risk-reducing surgery) for individuals with positive results, individuals with negative results, and key differences between the two; and
      - Potential for uninformative or uncertain test results; and
      - Potential that test results may provide health information regarding the risk of disease for other family members.

  *Genetics professionals are not excluded if they are employed by or contracted with a laboratory that is part of an Integrated Health System which routinely delivers health care services beyond just the laboratory test itself.

  II. <u>Known Familial Mutation</u>

  Single-site (known familial variant) analysis of *BRCA1* and/or *BRCA2* may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual who meets ALL of the following:
  - Genetic counseling criteria in section I have been met; **AND**

- Known familial mutation in BRCA1 and or BRCA2 identified in 1st, 2nd, or 3rd degree relative(s); **AND**
- No previous germline BRCA1 and/or BRCA2 testing, or results of previous testing were incomplete.

III. Personal History of Cancer

Genetic testing of *BRCA1* and/or *BRCA2* may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual who meets **ALL** of the following:

- Testing recommended by the treating surgeon, ~~or~~ oncologist, or genetic counselor; **AND**
- Personal history of one or more of the following at any age:
  - Breast cancer
  - Ovarian cancer
  - Fallopian tube cancer
  - Primary peritoneal cancer
  - Pancreatic cancer
  - Prostate cancer that meets at least one of the following:
    1. Metastatic; or
    2. Intraductal/cribriform histology; or
    3. High or very-high risk group defined as any of the following:
       - Gleason score ≥ 8; or
       - T stage of T3a, T3b, or T4; or
       - PSA > 20 ng/mL; or
       - Gleason pattern 5 histology; or
    4. Ashkenazi Jewish ancestry; or
    5. One or more close blood relative(s) with:
       - breast cancer age ≤ 50 years; or
       - colorectal cancer age ≤ 50 years; or
       - endometrial cancer age ≤ 50 years; or
       - ovarian cancer at any age; or
       - pancreatic cancer at any age; or
       - metastatic, regional, very-high risk, high risk prostate cancer at any age; or
    6. Two or more close blood relatives, on the same side of the family, with breast or prostate cancer at any age; or

  AND
- No previous germline *BRCA1* and/or *BRCA2* testing; or results of previous testing were incomplete.

IV. Predisposition Testing in Individuals with No Personal History of Cancers in Section III

Genetic testing of BRCA1 and/or BRCA2 may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for an individual with no personal history of cancers listed in section III of this policy who meets **ALL** of the following:

- Genetic counseling criteria in section I have been met; **AND**
- A first-or second-degree blood relative meets any of the criteria in section III of this policy; **AND**
- Has a reasonable likelihood of a mutation based on pre-test genetic counseling; **AND**
- Unaffected member is the most informative person to test. All affected family members are deceased, or all affected family members have been contacted and are unwilling to be tested; **AND**
- No previous germline BRCA1 and/or BRCA2 testing; or results of previous testing were incomplete.

V. Multi-Gene Panel Sequencing

Genetic testing for hereditary breast and/or ovarian cancer using a multi-gene sequencing panel that includes *BRCA1/BRCA2* genes is considered **MEDICALLY NECESSARY AND APPROPRIATE** when an individual meets **ALL** of the following:

- Genetic counseling meeting criteria in section I documents a family history/pedigree demonstrating a reasonable likelihood for one of the following cancer syndromes (associated genes in parentheses):

- Bannayan-Riley-Ruvalcaba syndromes, Cowden syndrome, PTEN hamartoma syndrome (*PTEN*)
- Hereditary diffuse gastric cancer syndrome (*CDH1*)
- Li Fraumeni syndrome (TP53)
- Lynch syndrome/hereditary non-polyposis colorectal cancer (*MSH2, MLH1, MSH6, MUYH, PMS2, PMS1, EPCAM*)
- PALB2 genetic mutation associated with increased risk of breast cancer (*PALB2*)
- Peutz-Jeghers syndrome (*STK11*)

AND

- Unaffected member is the most informative person to test. All affected family members are deceased, or all affected family members have been contacted and are unwilling to be tested; **AND**
- The majority of genes in the panel have a proven association with breast and/or ovarian cancer (e.g. *ATM*, BRCA1, BRCA2, *BRIP1, CDH1, CHEK2, MLH1, MSH2, MSH6, PALB2, PTEN, STK11, TP53*); **AND**
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance).

VI. Experimental/Investigative

Genetic testing for hereditary breast and/or ovarian cancer as either a single-gene or multi-gene panel test is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an effect on health outcomes:

- Testing will not affect treatment or surveillance decisions
- Testing offered as a direct access (also known as direct to consumer)
- Testing in the general population as a screening tool
- All other testing for risk of hereditary breast and/or ovarian cancer that do not meet criteria as stated above.

Documentation Submission:

Documentation from the ordering clinician supporting the medical necessity criteria in the policy must be included in the prior authorization. In addition, the following documentation must be submitted:

- The request states the specific test(s) name and included genes, AND
- Documentation from the clinical notes that criteria for genetic counseling (if required) have been met, AND
- Documentation of one of the following:
  - Known deleterious mutation in genes addressed in this policy in a close blood relative; OR
  - Diagnosis of individual with personal history of cancers addressed in this policy; OR
  - Results of pedigree indicating need for testing in individual with family history only; OR
  - Results of pedigree and genes for which multigene panel testing is indicated.

- **Intraosseous Nerve Ablation for Chronic Low Back Pain, IV-111**

I. Intraosseous basivertebral nerve ablation (i.e., Intracept®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of vertebrogenic pain including **ALL** of the following:
  - Modic Type 1 or Type 2 changes in at least one vertebral endplate at one or more levels from L3-S1; **AND**
  - Absence of non-vertebrogenic pathology, including but not limited to fracture, tumor, infection, significant deformity, trauma, or post-surgical change;

AND

- Skeletally mature; **AND**
- Chronic low back pain (CLBP) present for at least 6 months; **AND**
- At least 6 months of continuous, professionally directed non-surgical medical management, including 3 or more of the following:
  - Avoidance of activities that aggravate pain;

- Chiropractic manipulation;
- Course of physical therapy or professionally directed therapeutic exercise program;
- Injection therapy (e.g., epidural, facet);
- Pharmacotherapy (e.g., non-narcotic analgesics, anti-inflammatories, muscle relaxants, neuroleptics, and narcotics);

AND

- Radiographic evidence shows absence of another etiology for the individual's symptoms (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain); **AND**
- **NONE** of the following:
  - Disc extrusion or protrusion > 5 mm; OR
  - Spondylolisthesis > 2 mm at any level; OR
  - Metabolic bone disease (e.g., osteoporosis), spine fragility fracture, trauma/compression fracture, or spinal cancer; OR
  - Spine infection or active systemic infection; OR
  - Previous lumbar/lumbosacral spine surgery at the intended treatment level; OR
  - Presence of active implantable pulse generators (e.g., pacemakers, defibrillators); OR
  - Neurogenic claudication, lumbar radiculopathy or radicular pain due to neurocompression as primary symptoms; OR
  - Severe cardiac or pulmonary compromise, systemic vulnerability to bleeding, or concern for further compromise of existing disease.

II. Intraosseous basivertebral nerve ablation (i.e., Intracept®) is considered **EXPERIMENTAL/INVESTIGATIVE** when the above criteria are not met, and for all other indications, due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

1. Clinical notes documenting ALL of the following:
   - Diagnosis and clinical features of the diagnosis, including Modic changes and absence of nonvertebrogenic pathology;
   - History of chronic low back pain of at least 6 months duration;
   - Documentation of current and previous non-surgical medical management;
   - Documentation of the absence of another etiology for the patient's symptoms, and all other exclusions noted in the criteria.
2. Imaging confirms Modic Type 1 or 2 changes of the vertebral endplates at one or more levels from L3-S1.
3. Imaging confirms absence of another etiology for the individual's symptoms (e.g., lumbar spinal stenosis, spondylolisthesis, segmental instability, disc herniation, degenerative scoliosis, facet arthropathy or effusion with clinically suspected facet joint pain).

- **Luspatercept (Reblozyl), II-237**

I. <u>Initial Review for Luspatercept (Reblozyl®) for Beta Thalassemia</u>

Luspatercept may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 18 years or older; **AND**
- Absence of sickle beta thalassemia or alpha thalassemia; **AND**
- Anemia in patients with a diagnosis of beta thalassemia (including beta+ thalassemia, beta^0 thalassemia, and hemoglobin E beta thalassemia); **AND**

- Required transfusion of ≥ 6 RBC units in the 24 weeks prior; **AND**
- Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of beta thalassemia; **AND**
- No FDA labeled contraindications to luspatercept (see table 1 below); **AND**
- Dose is within the FDA labeled dose for the indication (see table 2 below).

II. <u>Renewal Review for Luspatercept (Reblozyl®) for Beta Thalassemia</u>

Luspatercept may be considered M**EDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for luspatercept through the initial review process; **AND**
- ONE of the following while treated with maximal dose of luspatercept (1.25 mg/kg once every 3 weeks):
  - Demonstrated a minimum of one-third reduction in RBC transfusions; OR
  - Achieved ≥ 2 unit reduction in RBC units over a minimum 12-week period compared to RBC units transfused during similar period prior to treatment with luspatercept;

  AND
- Prescribed by, or in consultation with, a hematologist or other specialist with expertise in the diagnosis and management of beta thalassemia; **AND**
- No FDA labeled contraindications to luspatercept (see table 1 below); **AND**
- Dose is within the FDA labeled dose for the indication (see table 2 below).

III. <u>Initial Review of Luspatercept (Reblozyl®) for Myelodysplastic Syndromes or Myelodysplastic/ Myeloproliferative Neoplasm</u>

Luspatercept may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 18 years or older; **AND**
- Diagnosis of ONE of the following:
  - Myelodysplastic syndromes; OR
  - Myelodysplastic/myeloproliferative neoplasm;

  AND
- Documented lower risk disease defined by one of the following:
  - Revised International Prognostic Scoring System (IPSS-R): very low, low, intermediate (Score 0 to ≤ 4.5); OR
  - IPSS: low/intermediate-1 (Score 0 to 1); OR
  - World Health Organization-Based Prognostic Scoring System (WPSS): very low, low, Intermediate (Score 0 to 2);

  AND
- **BOTH** of the following:
  - Hemoglobin <10 g/dL; AND
  - Required transfusion of at least 2 units of packed red blood cells (pRBCs) in the prior 8 weeks;

  AND
- ONE of the following:
  - Sideroblastic anemia AND BOTH of the following:
    - ONE of the following:
      - Ring sideroblasts ≥ 15%; OR
      - Ring sideroblasts ≥ 5% with an SF3B1 mutation;

      AND

- ONE of the following:
  - Ineligible for erythropoiesis stimulating agent (ESA) therapy (e.g., serum erythropoietin > 500 U/L); OR
  - Disease not responsive to prior treatment with an ESA; OR
  - Prior ESA therapy discontinued due to adverse event;

OR

- Anemia with blasts < 5% in bone marrow AND BOTH of the following:
  - No prior treatment with an erythropoiesis stimulating agent (ESA) (i.e., ESA naïve); AND
  - Serum erythropoietin < 500 U/L;

AND

- Other causes of anemia (e.g., gastrointestinal bleeding, hemolysis, renal disease, nutritional deficiency, etc.) have been ruled out and/or addressed; **AND**
- Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **AND**
- No FDA labeled contraindications to luspatercept (see table 1 below); **AND**
- Dose is within the FDA labeled dose for the indication (see table 2 below).

IV. Renewal Review of Luspatercept (Reblozyl®) for Myelodysplastic Syndromes or Myelodysplastic/Myeloproliferative Neoplasm

Luspatercept may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for luspatercept through the initial review process; **AND**
- ONE of the following while treated with maximal dose of luspatercept (1.75 mg/kg once every 3 weeks):
  - In low transfusion burden patients (2-7 RBC units in 16 weeks), demonstrated absence of any transfusions for 8 weeks over a period of 24 weeks; OR
  - In high transfusion burden patients (≥ 8 RBC units in 16 weeks), demonstrated a reduction of at least 50% of RBC units over a minimum 16-week period;

AND

- Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **AND**
- No FDA labeled contraindications to luspatercept (see table 1 below); **AND**
- Dose is within the FDA labeled dose for the indication (see table 2 below).

V. Experimental / Investigative Uses

All other uses of luspatercept, including but not limited to non-transfusion-dependent beta-thalassemia, and treatment of patients not meeting the criteria above, are considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Luspatercept (Reblozyl®)	None

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is outside of the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Anemia in patients with beta thalassemia	1 mg/kg once every 3 weeks by subcutaneous injection administered by a healthcare professional, with maximum dose of 1.25 mg/kg every 3 weeks. Discontinue treatment if no reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.25 mg/kg.
Anemia in patients with: Myelodysplastic Syndromes or Myelodysplastic/Myeloproliferative Neoplasm	1 mg/kg once every 3 weeks by subcutaneous injection administered by a healthcare professional, with maximum dose of 1.75 mg/kg every 3 weeks. Discontinue treatment if no reduction in RBC transfusion burden after 3 consecutive doses (9 weeks) at 1.75 mg/kg.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization, when prior authorization is required. In addition, the following documentation must also be submitted:

Initial Review

- Clinical notes describing the diagnosis and clinical features of the diagnosis, including the frequency of RBC transfusions.
- The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose must be submitted, including prior dosing (strength and frequency) associated with inadequate response.

Renewal Review

- Documentation of prior approval for luspatercept through the initial review process.
- Documentation, since most recent approval, demonstrating reduced red blood cell transfusion burden while treated with luspatercept.
  - For anemia in patients with beta thalassemia, baseline RBC unit transfusion requirements over a minimum 12-week period and over a similar period while on luspatercept.
  - For anemia in patients with myelodysplastic syndromes or myelodysplastic/myeloproliferative neoplasms, baseline RBC unit transfusion requirements over a minimum 16-week period and over a similar period while on luspatercept.
- The dose being requested. If the requested dose is outside of the dosing criteria provided in the table above, a clear explanation for the medical necessity of the requested dose must be submitted, including prior dosing (strength and frequency) associated with inadequate response.

- **Prolotherapy, II-06**

Prolotherapy is considered **EXPERIMENTAL/INVESTIGATIVE** for all indications due to a lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Single-Nucleotide Polymorphism (SNP) Breast Cancer Risk Assessment, VI-32**
  Testing for one or more single nucleotide polymorphisms, as a method for estimating individual patient risk for developing breast cancer, is considered **EXPERIMENTAL/ INVESTIGATIVE** due to a lack of evidence demonstrating impact on improved health outcomes.

Policies Delegated to eviCore
None

Policies Inactivated
None