Independence Blue Cross

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CODING GUIDELINES AND POLICY UPDATE

www.ibx.com/medpolicy

Important Note:

The medical policies referenced in this document apply to all HMO, POS, and PPO products of Independence Blue Cross ("IBC"), including its affiliates, as well as to traditional indemnity products to the extent the applicable covered services are underwritten by IBC or its affiliates. Please note that some of IBC's traditional indemnity products are jointly underwritten by Highmark Blue Shield and therefore Highmark's medical policy may apply. You may refer to the member's ID card for the entity that is responsible for underwriting the product.

This document was developed to assist IBC in administering the provisions of its benefits programs and does not constitute medical advice. Professional providers are responsible for providing medical advice and treatment. Even though this document may conclude that a particular service or item is medically necessary, such conclusion is NOT based upon the terms of a particular member's benefit plan. Members must refer to their specific benefit program for the terms, conditions, limitations and exclusions of coverage.

Please note that the Policy Bulletins which are referenced herein describe the status of a specific topic at the time the Policy Bulletin was created. Policy Bulletins are updated biennially and when new medical evidence becomes available, therefore, they are subject to change.

Please be aware that the actual Policy Bulletins which are discussed herein are used as a guide only. Coverage decisions are made on a case-by-case basis by applying Policy Bulletin criteria to the member's medical history, condition, and proposed course of treatment as well as the member's benefit program. Providers should review Policy Bulletins with Members as treatment options are discussed, as the Policy Bulletins are designed to be used by our professional staff in making coverage determinations and can be highly technical.

Information contained in this document and the actual Policy Bulletin does not constitute an offer of coverage, medical advice, or guarantee of payment. Please note that, if there is a conflict between the Policy Bulletin and a member's benefit program, the terms of the benefit program will govern.

Please note that providers who opted out of the class action settlement may not be entitled to certain claim payment policy changes. Therefore, any payments made pursuant to such policy changes to providers who opted out of the class action settlement are subject to retroactive adjustments.

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View Full Policies Online

The descriptions provided in this document are summaries. Full descriptions of these policies are available online at *www.ibx.com/medpolicy* under the Medical section.

Medical Policies

Agalsidase beta (Fabrazyme®) (08.00.69)

Covered: According to Certain Criteria

Fabry disease is a rare gene mutation disorder that is inherited in an X-linked recessive pattern. Since the altered gene is carried on a mother's X chromosome, sons have a fifty-percent chance of inheriting the disorder, and daughters have a fifty-percent chance of being a carrier. Some female carriers may also exhibit symptoms, especially cloudiness of the cornea.

Agalsidase beta (Fabrazyme®) is an enzyme that is almost identical to the enzyme produced in the human body. The replacement of the missing lysosomal enzyme reduces a particular type of lipid (fat) accumulation in many types of cells, including blood vessels in the kidneys and other organs. With the reduction of fat deposition, it is believed that life-threatening organ damage will be prevented.

Agalsidase beta (Fabrazyme®) is considered medically necessary and, therefore, covered for individuals with Fabry disease to reduce globotriaosylceramide (GL-3) deposition in capillary endothelium of the kidney and certain other cell types.

All other uses for agalsidase beta (Fabrazyme®) are considered experimental/investigational and, therefore are not covered because their safety and/or efficacy cannot be established by review of the available published literature.

There is no Medicare coverage determination addressing this drug. For Medicare Advantage members, agalsidase beta (Fabrazyme®) infusions are solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

U.S. Food and Drug Administration (FDA)-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Bevacizumab (Avastin®) (08.00.66)

Covered: According to Certain Criteria

Bevacizumab (Avastin®) is a recombinant humanized monoclonal antibody that works by binding to and inhibiting the action of vascular endothelial growth factor (VEGF). VEGF is a substance that binds to certain cells to stimulate new blood vessel formation (angiogenesis). When VEGF is bound to bevacizumab (Avastin®), it cannot stimulate the formation and growth of new blood vessels.

Bevacizumab (Avastin®) enhances the effects of chemotherapy, but it does not appear to be effective when given alone.

Bevacizumab (Avastin®) is considered medically necessary and, therefore, covered for the following indications:

Colorectal Carcinoma

- In individuals who have metastatic carcinoma of the colon or rectum, as first- or second-line treatment, in combination with intravenous 5-fluorouracil-based chemotherapy

Non-Squamous Non-Small Cell Lung Cancer

- In individuals who have unresectable, locally advanced, recurrent, or metastatic non-squamous non-small cell lung cancer, as first-line treatment in combination with paclitaxel and carboplatin

Breast Carcinoma

- In individuals who have HER2-negative metastatic breast carcinoma, as first-line treatment in combination with paclitaxel

Macular Degeneration

- In individuals who have wet, age-related macular degeneration (AMD), as treatment by intravitreal injection
  - Intravitreal injection of bevacizumab (Avastin®) for macular degeneration must be reported with both of the following codes:
    - 67028: Intravitreal injection of a pharmacologic agent (separate procedure)
    - J3490: Unclassified drugs

All other uses of bevacizumab (Avastin®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

This policy is consistent with Medicare's coverage determination. For Medicare Advantage members, bevacizumab (Avastin®) infusions are solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Cetuximab (Erbitux™) (08.00.67)

Covered: According to Certain Criteria

Cetuximab (Erbitux™) is a type of drug known as a monoclonal antibody. Monoclonal antibodies may be used to try to destroy some types of cancer cells while causing little harm to normal cells. They are designed to recognize certain proteins (known as epidermal growth factor receptors [EGFRs]) that are found on the surface of particular cancer cells. When growth factors bind to the receptor, the cancer cell is stimulated to grow, divide, and spread.

Cetuximab (Erbitux™) attaches itself to the EGFRs and prevents the receptors from being activated. This stops the cells from dividing. It therefore has the potential to stop the cancer cells from growing. It works in a way that is different from both chemotherapy and hormonal therapy. Cetuximab (Erbitux™) may also make the cancer cells more sensitive to chemotherapy.

Cetuximab (Erbitux™) is considered medically necessary and, therefore, covered for the following indications:

Colorectal Cancer

Intravenous cetuximab (Erbitux™), used in combination with irinotecan, is indicated for the treatment of metastatic colorectal cancer in individuals who are refractory to irinotecan-based chemotherapy (i.e., the tumor response rate was poor/progression was not halted).

Cetuximab (Erbitux™) administered intravenously as a single agent is indicated for the treatment of metastatic colorectal cancer in individuals who are intolerant to irinotecan-based chemotherapy (e.g., they experience severe gastrointestinal reactions and/or pulmonary complications).

Head and Neck Cancer

Intravenous cetuximab (Erbitux™), used in combination with radiation therapy, is indicated for the treatment of locally or regionally advanced squamous cell cancer of the head and neck.

Cetuximab (Erbitux™) administered intravenously as a single agent is indicated for the treatment of individuals with recurrent or metastatic squamous cell cancer of the head and neck for whom prior platinum-based chemotherapy has failed.

All other uses for cetuximab (Erbitux™) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

This policy is consistent with Medicare's coverage determination. For Medicare Advantage members, cetuximab (Erbitux™) is solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Ibandronate Sodium (Boniva®) for Intravenous Injection (08.00.68)

Covered: According to Certain Criteria

Ibandronate sodium (Boniva®) intravenous (IV) injection is a nitrogen-containing bisphosphonate that inhibits osteoclast activity and reduces bone resorption and turnover. The action of ibandronate sodium (Boniva®) on bone tissue is based on its affinity for hydroxyapatite, which is part of the mineral matrix of bone.

Ibandronate sodium (Boniva®) IV injection has been shown to increase bone mineral density and reduce the incidence of vertebral fractures in postmenopausal women with osteoporosis.

Ibandronate sodium (Boniva®) IV injection is considered medically necessary and, therefore, covered for the treatment of osteoporosis in postmenopausal women who are either intolerant to, or have contraindications for, oral bisphosphonate therapy.

All other uses for ibandronate sodium (Boniva®) IV injection are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

There is no Medicare coverage determination addressing this drug. For Medicare Advantage members, ibandronate sodium (Boniva®) IV injections are solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Idursulfase (Elaprase®) (08.00.71)

Covered: According to Certain Criteria

Hunter syndrome, also known as mucopolysaccharidosis II (MPS II), is a rare, life-threatening, X-linked genetic disorder. Individuals with Hunter syndrome lack the enzyme iduronate-2-sulfatase, which is essential in the continuous process of replacing and breaking down glycosaminoglycans (GAGs). GAGs are the most abundant heteropolysaccharides in the human body and play an important role in neuron communication. As a result of the enzyme deficiency, GAGs remain stored in the cells of the body and cause progressive damage.

Idursulfase (Elaprase®) was approved by the FDA as an orphan drug (a drug used to treat, prevent, or diagnose a rare disease); it is manufactured using recombinant DNA technology. The result is the production of an enzyme that is almost identical to the enzyme produced in the human body. Treatment allows the body to uptake the enzyme into cellular lysosomes which aids in the catabolism of accumulated GAG.

Idursulfase (Elaprase®) is considered medically necessary and, therefore, covered for the treatment of Hunter syndrome.

All other uses for idursulfase (Elaprase®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

There is no Medicare coverage determination addressing this drug. For Medicare Advantage members, idursulfase (Elaprase®) infusions are solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Laronidase (Aldurazyme®) (08.00.70)

Covered: According to Certain Criteria

Mucopolysaccharidosis type I (MPS I), also known as Hurler syndrome, is an inherited and progressive condition that results in the deficiency of alpha-L-iduronate, which is a lysosomal enzyme that helps break down materials called glycosaminoglycans (GAGs), or mucopolysaccharides. GAGs, which are long chains of sugar carbohydrates found in cells of the body, help build bone, cartilage, tendons, corneas, skin, and connective tissue; they are also found in the fluid that lubricates joints. Without the adequate breakdown of GAGs, there is an accumulation of the materials that ultimately leads to cell, tissue, and organ dysfunction.

Laronidase (Aldurazyme®) was approved by the FDA as an orphan drug (a drug used to treat, prevent, or diagnose a rare disease); it is manufactured using recombinant DNA technology. The result is the production of an enzyme that is almost identical to the enzyme produced in the human body. Treatment of MPS I allows the body to uptake the enzyme into cellular lysosomes, which aids in the catabolism of accumulated GAGs.

Laronidase (Aldurazyme®) is considered medically necessary and, therefore, covered for use in individuals with the following subtypes of MPS I:

- Severe MPS I: Hurler syndrome (MPS I H)
- Intermediate MPS I: Hurler-Scheie syndrome (MPS I H-S)
- Mild MPS I: Scheie syndrome (MPS I S)

All other uses for laronidase (Aldurazyme®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

There is no Medicare coverage determination addressing this drug. For Medicare Advantage members, laronidase (Aldurazyme®) infusions are solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Natalizumab (TYSABRI®) (08.00.64)

Covered: According to Certain Criteria

Natalizumab (TYSABRI®) is a recombinant humanized monoclonal antibody that binds to the α4-subunit of the α4ß1 and α4ß7 integrins expressed on the surface of all leukocytes except neutrophils, and inhibits the α4-mediated adhesion of leukocytes to their counter-receptor(s). The clinical effect of natalizumab (TYSABRI®) in multiple sclerosis (MS) may be secondary to blockade of the molecular interaction of the α4ßl-integrin expressed by inflammatory cells with vascular cell adhesion molecule-1 on vascular endothelial cells, and with CS-L and/or osteopontin expressed by parenchymal cells in the brain. Data from an experimental autoimmune encephalitis animal model of MS demonstrate the reduction of leukocyte migration into the brain parenchyma and the reduction of plaque formation detected by magnetic resonance imaging, following repeated administration of natalizumab (TYSABRI®).

Natalizumab (TYSABRI®) is considered medically necessary and, therefore, covered as monotherapy for the treatment of adults with relapsing forms of MS to delay the accumulation of physical disability and to reduce the frequency of clinical exacerbations when both of the following criteria are met:

- Natalizumab (TYSABRI®) is prescribed by a neurologist.
- An individual has had an inadequate response to, or is unable to tolerate, alternate MS therapies (e.g., Avonex®, Rebif®, Betaseron®).

All other uses for natalizumab (TYSABRI®) are considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of natalizumab (TYSABRI®) in the diagnosis or treatment of other conditions cannot be established by review of the available published literature.

There is no Medicare coverage determination addressing this drug. For Medicare Advantage members, natalizumab (TYSABRI®) is solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Pamidronate Disodium (Aredia®) (08.00.65)

Covered: According to Certain Criteria

Pamidronate disodium (Aredia®), a synthetic bisphosphonate analog of pyrophosphate, is a bone-resorption inhibitor which either directly blocks the dissolution of calcium phosphate in the bone by adhering to a chemical compound in the drug or which inhibits osteoclast activity. Pamidronate disodium (Aredia®) is only available for intravenous infusions.

Pamidronate disodium (Aredia®) is considered medically necessary and, therefore, covered for individuals with *any* of the following conditions:

- Hypercalcemia of malignancy
  - For the treatment of moderate or severe hypercalcemia associated with malignancy, with or without bone metastases
- Paget's disease
  - For the treatment of moderate to severe Paget's disease of bone
- Osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma
- Osteogenesis imperfecta
- Disabling osteoporosis, when *all* of the following medical necessity criteria are met:
  - The individual has a T-score less than or equal to -2.5.
    - A T-score is determined by comparing the results of an individual's bone mineral density (BMD) test with the results that are normally found in a healthy young adult of the same gender. The T-score is the number of units (standard deviations) above (+) or below (-) what is considered to be standard.
  - The individual is at risk for compression fractures of the axial skeleton *or* for peripheral fractures.
  - The use of calcitonin is contraindicated because the individual has an allergy to shellfish and/or salmon derivatives *or* the individual has already failed a trial of calcitonin.
  - The individual is unable to take oral bisphosphonates *or* has failed a 12-month trial of oral bisphosphonates *or* the individual's condition has severely deteriorated and the osteoporosis is so significant that a trial of oral bisphosphonates is not medically warranted.
- Osteopenia, when *all* of the following medical necessity criteria are met:
  - The individual has a T-score less than -1.5.
  - The individual is at risk for compression fractures.
  - The use of calcitonin is contraindicated because the individual has an allergy to shellfish and/or salmon derivatives *or* the individual has already failed a trial of calcitonin.
  - The individual is unable to take oral bisphosphonates *or* has failed a 12-month trial of oral bisphosphonates *or* the individual's condition has severely deteriorated and the osteoporosis is so significant that a trial of oral bisphosphonates is not medically warranted.
  - The individual has pain and difficulty with activities of daily living (ADLs) and/or ambulation secondary to the osteopenia.

All other uses for pamidronate disodium (Aredia®) are considered experimental/investigational and, therefore, not covered because their safety and/or efficacy cannot be established by review of the available published literature.

This policy is consistent with Medicare's coverage determination. For Medicare Advantage members, pamidronate disodium (Aredia®) is solely available under the medical benefit (Part B benefit). This drug is not covered under the pharmacy benefit (Part D benefit).

FDA-approved indications for this injectable can be found online at *www.ibx.com/medpolicy*. Please visit the website to view this information and the policy in its entirety.

Photodynamic Therapy (PDT) Using Levulan® Kerastick® (Aminolevulinic Acid [ALA]) (07.07.03b)

Covered: According to Certain Criteria

Photodynamic therapy (PDT) is a medical procedure that involves the administration of a photosensitive (light-activated) drug with a very specific absorption peak. The drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body topically, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. The administration of the photosensitive drug is followed by the targeted irradiation of affected tissue with a nonthermal laser calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. This activates the drug, enabling it to locally treat the diseased tissue.

PDT using Levulan® Kerastick® and the BLU-U Light Photodynamic Therapy Illuminator™ is considered medically necessary and, therefore, covered for the following FDA-approved indication:

- Treatment of non-hyperkeratotic actinic keratoses of the face and scalp

The BLU-U Light Photodynamic Therapy Illuminator™ was approved by the FDA for use in PDT in combination with Levulan® Kerastick® only for the FDA-approved indication listed above. PDT using Levulan® Kerastick® and the BLU-U Light Photodynamic Therapy Illuminator™ for any other indication is considered experimental/investigational and, therefore, not covered because the safety and/or efficacy of this device for other indications has not been established by a review of the available medical literature.

Obsolete or Unreliable Diagnostic Tests (00.01.24)

Not Covered: Considered Not Medically Necessary

Obsolete or unreliable diagnostic tests are defined as tests that are no longer routinely used and, in some instances, have become outdated and found to be of little clinical value. Some of these tests have been replaced with improved technology.

Lab Tests

The following diagnostic tests are considered obsolete or unreliable and have been replaced by more advanced testing procedures:

- Amylase, blood isoenzymes, electrophoretic
- Animal inoculation, small animal; with observation
- Animal inoculation, small animal; with observation and dissection
- Bendien's test for cancer and tuberculosis
- Bolen's test for cancer (Bolen's clot retraction test [CRT])
- Calcium, feces, 24-hour quantitative
- Calcium saturation clotting time
- Capillary fragility test (Rumpel-Leede)
- Cellular therapy
- Cephalin flocculation
- Chromium, blood
- Chymotrypsin, duodenal contents
- Circulation time, one test
- Colloidal gold
- Congo red, blood
- Gastric analysis, pepsin
- Gastric analysis, tubeless
- Guanase, blood
- Hair analysis
- Hormones, adrenocorticotropin quantitative animal tests

- Hormones, adrenocorticotropin quantitative bioassay
- Rehfuss test for gastric acidity
- Serum seromucoid assay for cancer and other diseases
- Skin test, actinomycosis
- Skin test, brucellosis
- Skin test, cat scratch fever (cat scratch disease; Bartonella infection)
- Skin test, lymphopathia venereum
- Skin test, psittacosis
- Skin test, trichinosis
- Starch, feces, screening
- Thymol turbidity, blood
- Zinc sulphate turbidity, blood

Cardiovascular Tests

Phonocardiography and vectorcardiography diagnostic tests have been determined to be obsolete and of little clinical value. They include:

- Intracardiac phonocardiogram
- Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report
- Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician)
- Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic)
- Phonocardiogram; without interpretation and report
- Phonocardiogram; interpretation and report only
- Vectorcardiogram (VCG), with or without ECG; with interpretation and report
- VCG; tracing only, without interpretation and report
- VCG; interpretation and report only

All tests listed in the policy are considered not medically necessary and, therefore, not covered.

Experimental/Investigational Policy

Lysis of Epidural Adhesions (11.15.13a)

Not Covered: Considered Experimental/ Investigational

Lysis of epidural adhesions using percutaneous injections of saline, steroid(s) anesthetic, and/or hyaluronidase into the epidural space has been investigated as a treatment option for lower back pain due to epidural fibrosis with or without adhesive arachnoiditis. Synonyms for lysis of epidural adhesions include the Racz procedure, epidurolysis, epidural neuroplasty, and epidural adhesiolysis.

There have been no well-designed investigations published in the peer-reviewed medical literature that support the safety and efficacy of the manipulation of an indwelling epidural Racz® Catheter or epidural injections of saline or hyaluronidase to relieve back pain in individuals with epidural adhesions, adhesive arachnoiditis, or failed back syndrome. Furthermore, evidence and rationale for routine use of the procedure outside of the research setting, with or without Racz® Catheter, are lacking. Evaluations done by national medical associations, consensus panels, and/or other technology evaluation bodies do not offer significant support for this procedure. The few small published studies on the lysing procedure leave important questions about its outcome, mechanism, and risk unanswered. In short, the available cumulative evidence for the efficacy of the procedure is preliminary and inconclusive.

Lysis of epidural adhesions is considered experimental/ investigational because the safety and/or efficacy of this procedure cannot be established by review of the available published literature. Therefore, this service is not covered.

More Information

Physician Volunteers Needed to Assist in Developing Medical Policies

Independence Blue Cross (IBC) is currently recruiting physicians to join our Policy Committee Advisory Panel. This panel is responsible for evaluating the scientific evidence and local standards of care addressed in our medical policies.

Medical policies are research-based documents that allow IBC to evaluate the medical necessity of services, devices, biologics, and procedures for its members. In addition, medical policies provide guidelines for obtaining benefits and reimbursement in accordance with a member's plan. As a volunteer consultant on the Policy Committee Advisory Panel, you will evaluate proposed medical policies based on your area(s) of expertise. As such, your contributions will significantly impact the care of patients in your region.

At this time, IBC is seeking physician consultants in the following specialties:

- Neurosurgery
- Orthopedics
- Urology
- Vascular Surgery
- Physical Medicine and Rehabilitation
- Rheumatology
- Cardiology
- Gastroenterology
- Pain Medicine

To qualify as a member of the Policy Committee Advisory Panel, you must:

- Maintain board certification for each specialty or subspecialty for which you wish to consult.
- Maintain an active clinical practice in each specialty or subspecialty for which you wish to consult.
- Understand and agree to adhere to our confidentiality statement.
- Maintain a high ethical standard, evidenced by the absence of any IBC investigation into personal or group claims practices.
- Complete and sign a Conflict of Interest Statement and Confidentiality Agreement prior to becoming a member of the advisory panel.

If you meet the above criteria and have an interest in sharing your expertise as a member of the Policy Committee Advisory Panel, please submit your curriculum vitae to:

Gerald W. Peden, M.D., M.A.
Senior Medical Director
Claim Payment Policy Department
Independence Blue Cross
1901 Market Street
Philadelphia, PA 19103-1480

Contact Provider Services

Provider Services	Philadelphia Area	Outside Philadelphia
HMO Policies/Procedures/Eligibility/Claims	(215) 567-3590	(800) 227-3119
PPO Policies/Procedures/Claims	(215) 567-3694	(800) 332-2566

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