Medical and Behavioral Health Policy Activity

Policies Effective: November 2, 2020 Notification Posted: September 1, 2020

Policies Developed

- **Romosozumab, II-236**

I. Initial Review for Romosozumab (Evenity™)

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

- Diagnosis of postmenopausal osteoporosis; **AND**
- ONE of the following:
  - Bone mineral density score of ≤ -2.5 at the total hip or femoral neck; OR
  - Bone mineral density score of ≤ -2.0 at the total hip or femoral neck and at least two vertebral fractures; OR
  - Bone mineral density score of ≤ -2.0 at the total hip or femoral neck and fracture of the proximal femur in the past 24 months;

  AND
- ONE of the following:
  - Previously tried and failed a bisphosphonate (oral or IV) and denosumab (Prolia®); OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to all bisphosphonates and denosumab (Prolia®);

  AND
- No history of myocardial infarction or stroke within the preceding year; **AND**
- No history or increased risk of osteonecrosis of the jaw; **AND**
- Not used in combination with a parathyroid hormone analog [e.g. abaloparatide (Tymlos®), teriparatide (Forteo®)], denosumab (Prolia®), or bisphosphonates; **AND**
- Prescribed by or in consultation with a specialist in treating osteoporosis (e.g. endocrinologist); **AND**
- No FDA labeled contraindications to romosozumab (see table 1 below); **AND**
- Dose is within the FDA labeled dose for the indication (see table 2 below); **AND**
- Romosozumab (Evenity™) will be administered as a consecutive treatment course once per lifetime; **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Romosozumab (Evenity™)

Use of romosozumab for greater than 12 months is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes. Romosozumab will only be approved for a consecutive course of therapy for ≤ 12 months once per lifetime.

III. Experimental/Investigative Uses

All other uses of romosozumab, including but not limited to use of romosozumab for greater than 12 months and restarting an incomplete course of therapy, 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
Romosozumab (Evenity™)	Hypocalcemia Known hypersensitivity to romosozumab

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Postmenopausal osteoporosis	210 mg once every month for 12 consecutive months by subcutaneous injection

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 medications for the diagnosis, including response to the medications.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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.
4. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

- ## Occipital Nerve Decompression, IV-167

Occipital nerve decompression is considered **EXPERIMENTAL/INVESTIGATIVE** for all uses, including but not limited to treatment of chronic headache, due to a lack of evidence demonstrating an impact on improved health outcomes.

- ## Inebilizumab, II-244

I. Initial Review for Inebilizumab (Uplizna™)

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

- Age 18 years or older; **AND**
- Diagnosis of neuromyelitis optica spectrum disorder (NMOSD); **AND**
- Positive serological test for aquaporin-4 (AQP4) antibodies; **AND**
- Clinical characteristics of NMOSD (e.g., optic neuritis, acute myelitis); **AND**
- ONE of the following:
  - History of a relapse that required rescue therapy (intravenous corticosteroid, intravenous immunoglobulin, and/or plasma exchange) during the previous 12 months prior to initiating inebilizumab; or
  - History of at least 2 relapses that required rescue therapy during the previous 24 months; **AND**
- Expanded Disability Status Scale (EDSS) score ≤8.0; **AND**
- No immunizations with live or live-attenuated vaccines within 4 weeks prior to initiation of treatment; **AND**
- Not used in combination with other biologic immunomodulators (e.g., rituximab, eculizumab); **AND**
- For patients not currently receiving inebilizumab, the patient has been screened for hepatitis B infection and has begun therapy if appropriate; **AND**
- For patients not currently receiving inebilizumab, the patient has been screened for tuberculosis and has begun therapy if appropriate; **AND**

- For patients not currently receiving inebilizumab, the patient has completed quantitative serum immunoglobulin testing which demonstrates sufficient levels that do not indicate immune compromise; **AND**
- No evidence of active infections; **AND**
- Prescribed by or in consultation with a specialist (e.g., neurologist); **AND**
- No FDA labeled contraindications to inebilizumab (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

II. Renewal Review for Inebilizumab (Uplizna™)

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

- Previously approved for inebilizumab through the initial review process; **AND**
- Demonstrated positive clinical response to inebilizumab therapy (e.g., reduced rates of relapses, improvement or stabilization of paralysis); **AND**
- Not used in combination with other biologic immunomodulators (e.g. rituximab, eculizumab); **AND**
- No evidence of active infections; **AND**
- Prescribed by or in consultation with a specialist (e.g., neurologist); **AND**
- No FDA labeled contraindications to inebilizumab (see table 1 below); **AND**
- The dose is within the FDA labeled dose (see table 2 below).

III. Experimental/Investigative Uses

All other uses of inebilizumab 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
Inebilizumab	• Previous life-threatening reaction to infusion of Uplizna™ • Active hepatitis B infection • Active or untreated latent tuberculosis

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD)	Initial dose: 300 mg intravenous infusion followed 2 weeks later by a second 300 mg intravenous infusion. Subsequent doses (starting 6 months from the first infusion): single 300 mg intravenous infusion every 6 months.

Documentation Submission:

Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization. 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 concomitant medications and pre-dose screening assessments.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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

1. Documentation of prior approval for inebilizumab through the initial review process.
2. Documentation supporting positive clinical response (e.g., slowing of disease progression or decrease in symptom severity and/or frequency).
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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.

- **Eptinezumab, II-240**

I. <u>Initial Review for Eptinezumab (Vyepti™)</u>

Eptinezumb (Vyepti™) 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:
  - **Episodic migraine headache** AND ALL of the following:
    - BOTH of the following for ≥3 months:
      - <15 headache days per month; and
      - 4 to 14 migraine days per month;

      AND
    - ONE of the following:
      - Tried and failed acute migraine therapies (e.g., triptans, 5HT-1F [Reyvow], ergotamines, acute CGRPs [Ubrelvy, Nurtec ODT]); or
      - Documented intolerance, FDA labeled contraindication, or hypersensitivity to acute migraine therapies;

    OR
  - **Chronic migraine headache** AND ALL of the following:
    - BOTH of the following for ≥3 months:
    - ≥15 headache days per month; and
    - ≥8 migraine days per month;

      AND
    - Prescribed by or in consultation with a headache specialist (e.g. neurologist; pain management specialist; or specialist with United Council for Neurologic Subspecialties [UCNS] certification);

  AND
- Medication overuse headache has been ruled out; **AND**
- ONE of the following:
  - Tried and failed a conventional agent prerequisite from at least two of the following migraine prophylaxis classes:
    - antidepressants (e.g., amitriptyline, venlafaxine);
    - calcium channel or beta blockers (e.g., propranolol, metoprolol, bisoprolol, verapamil);
    - anticonvulsants (e.g., topiramate, valproic acid);
    - botulinum toxin (Botox®);

OR

- Documented intolerance, FDA labeled contraindication, or hypersensitivity to conventional agents from at least two of the following migraine prophylaxis classes:
  - antidepressants (e.g., amitriptyline, venlafaxine);
  - calcium channel or beta blockers (e.g., propranolol, metoprolol, bisoprolol, verapamil);
  - anticonvulsants (e.g., topiramate, valproic acid);
  - botulinum toxin (Botox®);

AND

- ONE of the following:
  - Tried and failed BOTH erenumab (Aimovig®) and galcanezumab (Emgality®); OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to BOTH erenumab (Aimovig®) and galcanezumab (Emgality®);

AND

- Used of migraine prophylaxis; **AND**
- Not used in combination with botulinum toxin or another CGRP agent; **AND**
- No FDA labeled contraindications to eptinezumab (see Table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see Table 2 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

II. Renewal Review for Eptinezumab (Vyepti™)

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

- Previously approved for eptinezumab through the initial review process; **AND**
- ≥50% reduction in headache or migraine days per month from baseline (prior to therapy); **AND**
- Used for migraine prophylaxis; **AND**
- Not used in combination with botulinum toxin or another CGRP agent; **AND**
- For chronic migraine headache, prescribed by or in consultation with a headache specialist (e.g., neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties [UCNS] certification); **AND**
- No FDA labeled contraindications to eptinezumab (see Table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see Table 3 below).

III. Experimental/Investigative Uses

All other uses of eptinezumab 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
Eptinezumab (Vyepti™)	Serious hypersensitivity to eptinezumab or to any of the excipients

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Preventive treatment for episodic or chronic migraine headache	100 mg administered by intravenous infusion every 3 months. Some patients may benefit from a dosage of 300 mg administered by intravenous infusion every 3 months

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 medications for the diagnosis, including response to the medications. Clinical notes should include evaluation for potential medication overuse headache.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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.
4. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review
1. Documentation of prior approval for eptinezumab through the initial review process.
2. Documentation supporting reduction in headache or migraine days per month from baseline. Include information from the medical record and/or headache diary/log entries quantifying a reduction in migraine frequency or duration compared to baseline.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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

- **Botulinum Toxin, II-16**
  - **I. Abobotulinum Toxin A (Dysport®) Initial Review**

Abobotulinum toxin A (Dysport®) may be considered MEDICALLY NECESSARY AND APPROPRIATE when ALL of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 12 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles); OR
  - Hemifacial spasm; OR
  - Spasticity associated with ONE of the following conditions:
    - Cerebral palsy; OR
    - Stroke; OR
  - Spasticity of the lower limb; OR

- Spasticity of the upper limb;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

II. Abobotulinum Toxin A (Dysport®) Renewal Review

Abobotulinum toxin A (Dysport®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; AND
- Abobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); AND
- No FDA labeled contraindications to therapy (see table 1 below); AND
- Dose is within FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

III. Incobotulinum Toxin A (Xeomin®) Initial Review

Incobotulinum toxin A (Xeomin®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including essential blepharospasm of VII (facial) nerve disorders, in a patient 18 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles); OR
  - Spasticity of the upper limb; OR
  - Chronic sialorrhea **AND** ONE of the following:
    - Failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications (see table 2 below); **AND**
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

IV. Incobotulinum Toxin A (Xeomin®) Renewal Review

Incobotulinum toxin A (Xeomin®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**

- Incobotulinum toxin A treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); AND
- No FDA labeled contraindications to therapy (see table 1 below); AND
- Dose is within the FDA labeled dose for labeled indications (see table 2 below).

V. Onobotulinum Toxin A (Botox®) Initial Review

Onabotulinum toxin A (Botox®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Blepharospasm associated with dystonia, including benign essential blepharospasm or VII (facial) nerve disorders, in a patient 12 years of age or older; OR
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles); OR
  - Chronic anal fissures **AND** the following:
    - Failed one conventional therapy (e.g., bulking agents, sitz baths, laxatives, dietary changes, or 0.4% intra-anal nitroglycerin); OR
  - Chronic migraine headache in a patient 18 years of age or older **AND** ALL of the following:
    - ≥ 15 headache days per month for at least 3 months; **AND**
    - ≥ 8 migraine days per month for at least 3 months; **AND**
    - Medication overuse headache has been ruled out; **AND**
    - **ONE** of the following:
      - Tried and failed a conventional agent prerequisite from at least two of the following migraine prophylaxis classes:
        - antidepressants (e.g., amitriptyline, venlafaxine);
        - calcium channel or beta blockers (e.g., propranolol, metoprolol, bisoprolol, verapamil);
        - anticonvulsants (e.g., topiramate, valproic acid);
        - self-administered calcitonin gene-related (CGRPs) (i.e., erenumab [Aimovig], galcanezumab [Emgality];

        OR
      - Documented intolerance, FDA labeled contraindication, or hypersensitivity to conventional agents from at least two of the following migraine prophylaxis classes:
        - antidepressants (e.g., amitriptyline, venlafaxine);
        - calcium channel or beta blockers (e.g., propranolol, metoprolol, bisoprolol, verapamil);
        - anticonvulsants (e.g., topiramate, valproic acid);
        - self-administered calcitonin gene-related peptides (CGRPs) (i.e., erenumab [Aimovig], galcanezumab [Emgality]);

      AND
    - Use for migraine prophylaxis; **AND**
    - Not used in combination with a CGRP agent; **AND**
    - Prescribed by or in consultation with a headache specialist (e.g., neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties [UCNS] certification; OR
  - Dystonia associated with ONE of the following conditions:
    - Focal upper limb dystonia (e.g., organic writer's cramp); OR
    - Oromandibular dystonia (e.g., orofacial dyskinesia, jaw-closing dystonia, Meige syndrome); OR

- Laryngeal dystonia (adductor spasmodic dysphonia); OR
- Idiopathic (primary or genetic) torsion dystonia; OR
- Symptomatic (acquired) torsion dystonia; OR

- Esophageal achalasia **AND** ONE of the following:
  - Failed to respond to pneumatic dilation or myotomy; OR
  - Not a good candidate for pneumatic dilation or myotomy; OR
- Facial synkinesis; OR
- Hemifacial spasm; OR
- Overactive bladder **AND** ALL of the following:
  - Symptoms of urge urinary incontinence, urgency, and frequency; AND
  - Conservative therapies including bladder training, pelvic floor muscle exercises, and fluid management have been inadequate; AND
  - ONE of the following:
    - Failed two conventional agent prerequisites, including one anticholinergic agent (e.g., oxybutynin, tolterodine, trospium, darifenacin, solifenacin, or fesoterodine) AND mirabegron; OR
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one anticholinergic agent AND mirabegron. OR
- Palmar or axillary hyperhidrosis **AND** ONE of the following:
  - Failed aluminum chloride 20% solution; OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to aluminum chloride 20% solution; OR
- Sialorrhea **AND** ONE of the following:
  - Failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent; OR
- Spasticity associated with **ONE** of the following conditions:
  - Cerebral palsy; OR
  - Stroke; OR
  - Acquired spinal cord or traumatic brain injury; OR
  - Hereditary spastic paraplegia; OR
  - Spastic hemiplegia; OR
  - Neuromyelitis optica; OR
  - Multiple sclerosis; OR
    - Schilder's disease; OR
- Spasticity of the lower limb; OR
- Spasticity of the upper limb; OR
- Strabismus, including persistent cranial VI nerve palsy of one month or longer, in a patient 12 years of age or older **AND** ALL of the following:
  - Inadequate response to corrective lenses; AND
  - Inadequate response to any other additional, patient appropriate, conservative corrective therapies (e.g., exercises); AND
  - Good vision in both eyes; AND
  - Eye movements are not restricted; AND
  - Small to moderate angle of esotropia; AND
  - Potential for the patient to experience binocular vision; OR
- Urinary incontinence due to detrusor overactivity associated with a neurological condition (e.g., spinal cord injury, multiple sclerosis) **AND** ONE of the following:

- Failed two conventional agent prerequisites, including one anticholinergic agent (e.g., oxybutynin, tolterodine, trospium, darifenacin, solifenacin, or fesoterodine) AND mirabegron; OR
- Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one anticholinergic agent AND mirabegron;

AND

- No FDA labeled contraindications to therapy (see table 1 below); AND
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below); AND
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

VI. Onabotulinum Toxin A (Botox®) Renewal Review

Onabotulinum toxin A (Botox®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- ONE of the following:
  - Diagnosis of chronic migraine headache **AND** ALL of the following:
    - ≥50% reduction in headache or migraine days per month from baseline (prior to therapy); AND
    - Used for migraine prophylaxis; **AND**
    - Not used in combination with a CGRP agent; **AND**
    - Prescribed by or in consultation with a headache specialist (e.g., neurologist, pain management specialist, or specialist with United Council for Neurologic Subspecialties [UCNS] certification); OR
  - Another diagnosis AND reduction of symptom severity and/or frequency from baseline (prior to therapy);

AND

- No FDA labeled contraindication to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indication (see table 2 below).

VII. Rimabotulinum Toxin B (Myobloc®) Initial Review

Rimabotulinum toxin B (Myobloc®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of ONE of the following:
  - Cervical dystonia (spasmodic torticollis; applicable whether congenital, due to child birth injury, or traumatic injury) **AND** BOTH of the following:
    - Cervical dystonia must be associated with sustained head tilt or abnormal posturing with limited range of motion in the neck; AND
    - History of recurrent involuntary contraction(s) of one or more of the muscles of the neck (e.g., sternocleidomastoid, splenius, trapezius, or posterior cervical muscles); OR
  - Chronic sialorrhea AND ONE of the following:
    - Failed one conventional agent prerequisite (e.g., oral hyoscine, atropine drops, glycoprrolate, or amitriptyline); OR
    - Documented intolerance, FDA labeled contraindication, or hypersensitivity to at least one conventional agent;

AND

- No FDA labeled contraindications to therapy (see table 1 below); **AND**

- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

VIII. Rimabotulinum Toxin B (Myobloc®) Renewal Review

Rimabotulinum toxin B (Myobloc®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for therapy through the initial review process; **AND**
- Rimabotulinum toxin B treatment has resulted in a reduction of symptom severity and/or frequency from baseline (prior to therapy); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- Dose is within the FDA labeled dose for labeled indications or supported in literature for additional indications (see table 2 below).

IX. Cosmetic Indications

All other uses of abobotulinum toxin A, incobotulinum toxin A, onabotulinum toxin A, or rimabotulinum toxin B are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to the following conditions, due to the lack of clinical evidence demonstrating an impact on improved health outcomes:

- Bell's palsy
- Benign prostatic hyperplasia
- Chronic low back pain
- Chronic motor tic disorder, and tics associated with Tourette syndrome (motor tics)
- Depressive disorders
- Detrusor sphincteric dyssynergia
- Essential tremor
- Facial wound healing
- Gastroparesis
- Headaches, except as noted above for chronic migraine headache
- Hirschsprung's disease
- Internal anal sphincter (IAS) achalasia
- Interstitial cystitis
- Joint pain
- Lateral epicondylitis
- Mechanical neck disorders
- Myofascial pain syndrome
- Neuropathic pain after neck dissection
- Pain after hemorrhoidectomy or lumpectomy
- Prevention of pain associated with breast reconstruction after mastectomy
- Raynaud's disease/Raynaud's phenomenon
- Tinnitus
- Trigeminal neuralgia

Table 1. FDA Labeled Contraindications

Agent	FDA Labeled Contraindications
Abobotulinum toxin A (Dysport®)	Hypersensitivity; Allergy to cow's milk protein; Infection at the proposed injection site(s)
Incobotulinum toxin A (Xeomin®)	Hypersensitivity; Infection at the proposed injection site; For intradetrusor injections, urinary tract infection or urinary retention
Onabotulinum toxin A (Botox®)	Hypersensitivity; Infection at the proposed injection site; For intradetrusor injections, urinary tract infection or urinary retention
Rimabotulinum toxin B (Myobloc®	Hypersensitivity; Infection at the proposed injection site(s)

Table 2. Dosing

Onabotulinum Toxin A (Botox) Dosing (1 unit = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for onabotulinum toxin A (Botox®) is 400 units every 12 weeks.

FDA Labeled Indications	Maximum Treatment Dose	Maximum Billable Dose	Minimum Dosing Interval
Blepharospasm	Initial: 15 units (2.5 units into each of 3 sites per affected eye) Retreatment: 30 units (5 units into each of 3 sites per affected eye). Cumulative dose in 30 days should not exceed 200 units.	200 billable units	Every 12 weeks
Cervical dystonia	300 units divided among affected muscles	300 billable units	Every 12 weeks
Primary axillary hyperhidrosis	100 units (50 units per axilla)	100 billable units	Every 12 weeks

Chronic migraine prophylaxis	155 units divided across specific head/neck muscle areas	200 billable units	Every 12 weeks
Detrusor overactivity associated with a neurologic condition	200 units	200 billable units	Every 12 weeks
Overactive bladder	100 units	100 billable units	Every 12 weeks
Strabismus	Initial: 5 units per muscle Retreatment: 25 units per muscle	100 billable units	Every 12 weeks
Spasticity	400 units divided among affected muscles	400 billable units	Every 12 weeks
Off-Label Indications			
Achalasia	100 units (25 units per quadrant)	100 billable units	Every 6 months
Chronic anal fissure	25 units	100 billable units	Every 12 weeks
Facial synkinesis	100 units divided among affected muscles	100 billable units	Every 12 weeks
Focal limb dystonia	20 units divided among affected muscles	100 billable units	Every 12 weeks
Laryngeal dystonia (spasmodic dysphonia)	25 units	100 billable units	Every 12 weeks
Oromandibular dystonia	100 units per muscle	400 billable units	Every 12 weeks
Sialorrhea	260 units (100 units per parotid gland and 30 units per submandibular gland)	300 billable units	Every 12 weeks
Torsion dystonia	140 units	200 billable units	Every 12 weeks
Hemifacial spasm	25 units divided among affected muscles	100 billable units	Every 12 weeks
Primary palmar hyperhidrosis	100 units (50 units per palm)	100 billable units	Every 12 weeks

Abobotulinum Toxin A (Dysport) Dosing (5 units = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for abobotulinum toxin A (Dysport®) is 1,000 units every 12 weeks.

FDA Labeled Indications	Maximum Treatment Dose	Maximum Billable Dose	Minimum Dosing Interval
Cervical dystonia	Initial: 500 units divided	200 billable units	Every 12 weeks

	among affected muscles Retreatment: 1,000 units divided among affected muscles		
Spasticity in adults	1,500 units divided among affected muscles	300 billable units	Every 12 weeks
Spasticity in pediatric patients	30 units/kg or 1,000 units, whichever is lower, divided among affected muscles	200 billable units	Every 12 weeks
Off-Label Indications			
Blepharospasm	240 units (120 units per eye)	60 billable units	Every 12 weeks
Hemifacial spasm	220 units divided among affected muscles	60 billable units	Every 12 weeks

Rimabotulinum Toxin B (Myobloc) Dosing (100 units = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for rimabotulinum toxin B (Myobloc®) is 10,000 every 12 weeks.

FDA Labeled Indications	Maximum Treatment Dose	Maximum Billable Dose	Minimum Dosing Interval
Cervical dystonia	Initial: 5,000 units divided among affected muscles Retreatment: 10,000 units divided among affected muscles	100 billable units	Every 12 weeks
Off-Label Indications			
Sialorrhea	2,500 units (1,000 units per parotid gland and 250 units per submandibular gland)	25 billable units	Every 12 weeks

Incobotulinum Toxin A (Xeomin) Dosing (1 unit = 1 billable unit)

For one or more indications, unless otherwise stated below, the maximum cumulative dose for incobotulinum toxin A (Xeomin®) is 400 units every 12 weeks.

FDA Labeled Indications	MaximumTreatment Dose	Maximum Billable Dose	Minimum Dosing Interval
Blepharospasm	100 units (50 units per eye)	100 billable units	Every 12 weeks
Cervical dystonia	120 units divided among affected muscles	200 billable units	Every 12 weeks

Upper limb spasticity	400 units (both limbs) divided among affected muscles	400 billable units	Every 12 weeks
Chronic Sialorrhea	100 units divided with a ratio of 3:2 between parotid and submandibular glands	100 billable units	Every 16 weeks

Documentation Submission
Documentation supporting the medical necessity criteria described in the policy must be included in the prior authorization. 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. For onabotulinum toxin A (Botox®) requests to treat chronic migraine headache, clinical notes should include evaluation for potential medication overuse headache.
3. The dose being requested, including the patient's weight if the requested botulinum toxin agent and diagnosis require weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines provided 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.
4. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review
1. Documentation of prior approval for the requested botulinum toxin agent through the initial review process.
2. Documentation supporting reduction of symptom severity and/or frequency from baseline. For onabotulinum toxin A (Botox®) requests to treat chronic migraine headache, include information from the medical record and/or headache diary/log entries quantifying a reduction in migraine frequency or duration compared to baseline.
3. Clinical notes describing current and past treatments for the diagnosis, including response to the treatments.
4. The dose being requested, including the patient's weight if the requested botulinum toxin agent and diagnosis require weight-based dosing. If the requested dose is higher or more frequent than the dosing guidelines provided 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.

- **Drug Testing for Substance Use Disorder and Chronic Pain Management, VI-47**

I. <u>Presumptive Urine Drug Testing</u>

- Presumptive urine drug testing for substance use disorder treatment may be considered **MEDICALLY NECESSARY AND APPROPRIATE** under any of the following conditions:
  - On initial entrance into substance use disorder treatment when all of the following criteria are met:
    - An adequate clinical assessment of patient history and risk of substance use is performed, including obtaining information from the state prescription drug monitoring program; **AND**
    - Clinicians have knowledge of test interpretation; **AND**
    - Clinical documentation specifies how the test result will be used to guide clinical decision making.
  - During the stabilization phase of treatment, no more frequently than once a week for a maximum of 4 weeks.
  - During the maintenance phase of treatment:
    - First 4 weeks of maintenance: No more frequently than every 2 weeks;

- After 4 weeks of maintenance: No more frequently than once a month unless patient is demonstrating aberrant behavior defined by one or more of the following:
  - Lost prescriptions;
  - Requests for early refills;
  - Obtained controlled substances from multiple providers;
  - Unauthorized dose escalation;
  - Apparent intoxication.

- Presumptive urine drug testing for chronic pain management may be considered **MEDICALLY NECESSARY AND APPROPRIATE** under any of the following conditions:
  - On initial entrance into chronic pain management when all of the following criteria are met:
    - An adequate clinical assessment of patient history and risk of substance use is performed, including obtaining information from the state prescription drug monitoring program; **AND**
    - Clinicians have knowledge of test interpretation; **AND**
    - Clinical documentation specifies how the test result will be used to guide clinical decision making.
  - During subsequent monitoring of treatment no more frequently than the following times according to the risk level of the individual, as determined by a validated screening tool for assessing the risk of aberrant drug-related behaviors (e.g., the Opioid Risk Tool [ORT] or the Screener and Opioid Assessment for Patients with Pain-Revised [SOAPP-R]);
    - Twice a year for patients who are low or moderate risk;
    - Four times a year for patients who are high risk **OR** receiving an opioid dose >120 mg MED/d;
    - For patients demonstrating aberrant behavior defined by one or more of the following:
      - Lost prescriptions;
      - Requests for early refills;
      - Obtained controlled substances from multiple providers;
      - Unauthorized dose escalation;
      - Apparent intoxication.
- Presumptive urine drug testing is considered **NOT MEDICALLY NECESSARY** in all other situations, including but not limited to routine testing (e.g. "standing orders") and testing for non-medical purposes.

II. <u>Definitive Urine Drug Testing</u>

- Definitive urine drug testing for substance use disorder treatment or chronic pain management may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:
  - Presumptive urine drug testing was performed according to the medically necessary criteria described in section I; **AND**
  - The result of presumptive urine drug testing was one or more of the following:
    - Positive for a non-prescribed drug with abuse potential; **OR**
    - Positive for an illicit drug (e.g., methamphetamine or cocaine); **OR**
    - Negative for prescribed medications; **AND**
  - Clinical documentation specifies supporting rationale for each definitive test ordered; **AND**
  - Clinical documentation specifies how the test result will be used to guide clinical decision making.
- Definitive urine drug testing for substance use disorder treatment or chronic pain management may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **BOTH** of the following criteria are met:
  - A presumptive test for the relevant drug(s) is not commercially available; **AND**
  - The testing is performed according to the medically necessary criteria described in section I, with the exception that it is definitive rather than presumptive testing.
- Definitive urine drug testing is considered **NOT MEDICALLY NECESSARY** in all other situations, including but not limited to routine testing (e.g. "standing orders") and testing for non-medical purposes.

III. Drug testing using oral fluid or hair samples in outpatient substance use disorder treatment or outpatient chronic pain management settings is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

- **Burosumab, II-212**

I. Initial Review for Burosumab (Crysvita®)

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

- Diagnosis of ONE of the following:
  - **X-linked hypophosphatemia (XLH)** AND ALL of the following:
    - Age 6 months or older; **AND**
    - Diagnosis is confirmed by **ONE** of the following:
      - Genetic testing confirming *PHEX* gene mutation; or
      - Elevated serum fibroblast growth factor 23 (FGF23) based on laboratory reference range; **AND**
    - Presence of clinical signs and symptoms of disease, including but not limited to:
      - Rickets;
      - Growth retardation;
      - Musculoskeletal pain;
      - Bone fractures;

  OR
  - **FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO)** AND ALL of the following:
    - Age 2 years or older; **AND**
    - Diagnosis is confirmed by elevated serum fibroblast growth factor 23 (FGF23) based on laboratory reference range; **AND**
    - Hypophosphatemia is associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized; **AND**
    - Presence of clinical signs and symptoms of disease, including but not limited to:
      - Musculoskeletal pain;
      - Bone fractures;
      - Muscle weakness;

AND

- No use of oral phosphate or active vitamin D analogs within the past week; **AND**
- Fasting serum phosphorus concentration below the normal limit of the laboratory reference range for age; **AND**
- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders (e.g. endocrinologist, rheumatologist, nephrologist); **AND**
- No FDA labeled contraindications to burosumab (see table 1 below); **AND**
- Requested dose is within the FDA labeled dose for the labeled indications (see table 2 below); **AND**
- For commercial health plan members only, burosumab is administered in accordance with site of service criteria (see policy XI-06).

II. Renewal Review for Burosumab (Crysvita®)

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

- Previously approved for burosumab through the initial review process; **AND**
- Demonstrated positive clinical response to burosumab therapy (e.g., enhanced height velocity, improvement in skeletal deformities, reduction of fractures, reduction of generalized bone pain); **AND**
- Normalization of serum phosphate while on treatment; **AND**
- Prescribed by, or in consultation with, a specialist experienced in the treatment of metabolic bone disorders (e.g. endocrinologist, rheumatologist, nephrologist); **AND**
- No FDA labeled contraindications to therapy with burosumab (see table 1 below); **AND**

- Requested dose is within the FDA labeled dose for the labeled indications (see table 2 below); **AND**
- For commercial health plan members only, burosumab is administered in accordance with site of service criteria (see policy XI-06).

III. Experimental/Investigative Uses

The use of burosumab is considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications due to the lack of clinical evidence demonstrating an impact on improved health outcomes.

Table 1. FDA-Labeled Contraindications

Agent	FDA Labeled Contraindications
Burosumab (Crysvita®)	With oral phosphate and active vitamin D analogs Severe renal impairment or end stage renal disease When serum phosphorus is within or above the normal range for age.

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Pediatric patients with X-linked hypophosphatemia (6 months to less than 18 years of age)	For patients < 10 kg: 1 mg/kg of body weight rounded to the nearest 1 mg every 2 weeks. For patients ≥ 10 kg: 0.8 mg/kg of body weight, rounded to the nearest 10 mg, every 2 weeks. Minimum starting dose is 10 mg- maximum of 90 mg. See dose determination charts in the prescribing information for burosumab.
Adult patients with X-linked hypophosphatemia (18 years of age and older)	Up to 90 mg by subcutaneous injection every 4 weeks. Determine dose (mg) by body weight (kg) starting at 1 mg/kg of body weight rounded to the nearest 10 mg. Adjust dose by serum phosphorus level (mg/dL) See dose determination charts in the prescribing information for burosumab.
Pediatric patients with tumor-induced osteomalacia (2 years to less than 18 years of age)	0.4 mg/kg body weight administered every 2 weeks, rounded to the nearest 10mg, up to a maximum dose of 2 mg/kg not to exceed 180mg, administered every 2 weeks. Adjust dose by serum phosphorus level (mg/dL). See dose determination charts in the prescribing information for burosumab.
Adult patients with tumor-induced osteomalacia (18 years of age and older)	0.5 mg/kg body weight administered every 4 weeks, rounded to the nearest 10 mg, up to a maximum dose of 2 mg/kg not to exceed 180mg, administered every 2 weeks. Adjust dose by serum phosphorus level (mg/dL). See dose determination charts in the prescribing information for burosumab.

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

Initial Review
1. Clinical notes describing clinical signs and symptoms of disease.
2. Laboratory results confirming the diagnosis.
3. Laboratory results indicating serum phosphorus concentration below the normal limit for age.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines 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.
5. For commercial health plan members only, the site of service for burosumab is specified, including CMS place of service code (see policy XI-06). If burosumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

Renewal Review
1. Documentation of prior approval for burosumab through the initial review process.
2. Documentation supporting positive clinical response.
3. Laboratory results indicating normalization of serum phosphorus concentration while on treatment.
4. The dose being requested, including the patient's weight. If the requested dose is higher or more frequent than the dosing guidelines 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.
5. For commercial health plan members only, the site of service for burosumab is specified, including CMS place of service code (see policy XI-06). If burosumab is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- ## Liposuction, IV-82

NOTE: Coverage may be subject to legislative mandates, including but not limited to the following, which apply prior to the policy statements:
- Federal Women's Health and Cancer Rights Act (WHCRA)
- Minnesota Statute 62A.25 Reconstructive Surgery

Coverage

In accordance with the mandates listed above, liposuction is covered when performed as a breast reconstruction procedure following or in conjunction with mastectomy or breast-conserving surgery due to a diagnosis of breast cancer. This includes liposuction for treatment of physical complications of the mastectomy, including lymphedema.

Policy Position

I. Liposuction is **COSMETIC** when performed to enhance or otherwise alter physical appearance without correcting or improving a physiological function, except when performed as part of a covered breast reconstruction procedure

II. Use of liposuction (e.g., laser-assisted, ultrasound-assisted, and power-assisted) or suction-assisted protein lipectomy for any other indication, including but not limited to treatment of lipedema or lymphedema, is considered **EXPERIMENTAL/INVESTIGATIVE** due to a lack of evidence demonstrating improved health outcomes.

- **Surgical Treatments of Lymphedema, IV-158**

  Note: Suction assisted lipectomy/suction assisted protein lipectomy is addressed in medical policy IV-82, *Liposuction.*

  I. Surgical treatment of lymphedema, including but not limited to the following procedures, is considered **EXPERIMENTAL/INVESTIGATIVE** due to the lack of clinical evidence demonstrating an impact on improved health outcomes:
     - Vascularized lymph node transfer (VLNT);
     - Lymphaticovenous (lymphaticovenular) anastomosis (LVA);
     - Lymphovenous bypass;
     - Lymphatic-lymphatic bypass.

- **Bariatric Surgery, IV-19**

  I. Patient Selection Criteria: Initial Procedure

  The surgical treatment of morbid obesity may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for patients who meet **ALL** the following criteria:
  - Meets one of the following:
    - Age 18 years or older; OR
    - Bone age of ≥ 13 years in girls or ≥ 15 years in boys; OR
    - Attainment of 95% of adult height based on estimates of bone age;

    AND
  - Body mass index (BMI) of **ONE** of the following:
    - BMI of ≥ 40 kg/m^2 OR
    - BMI of 35 kg/m^2 to < 40 kg/m^2 with **AT LEAST ONE** of the following comorbid conditions:
      - Hypertension refractory to standard treatment; OR
      - Cardiovascular disease; OR
      - Type 2 diabetes mellitus (HbA_{1C} of 7 or greater, or requiring medication); OR
      - Obstructive sleep apnea requiring continuous positive airway pressure (CPAP) or other related treatment; OR
      - Obesity-hypoventilation syndrome (OHS); OR
      - Pickwickian syndrome (a combination of OSA and OHS); OR
      - Nonalcoholic fatty liver disease (NAFLD); OR
      - Nonalcoholic steatohepatitis (NASH); OR
      - Pseudotumor cerebri;

    AND
  - Patient has been evaluated by an eligible licensed mental health professional within 12 months prior to the surgery. The mental health professional's notes must document **ALL** of the following:
    - Absence of active substance use disorder; AND
    - If a mental health condition is present, it is under successful treatment; AND
    - Patient able to provide informed consent; AND
    - Personal barriers to making and continuing required life changes have been identified, and strategies to overcome those barriers have been recommended; AND
    - Family and social supports have been assessed, and strategies to strengthen those supports have been recommended;

    AND

- Patient has actively participated in a preoperative program supervised by a physician, physician's assistant, nurse practitioner/advanced practice nurse, or registered dietician. The supervising medical professional's notes must document **ALL** of the following:
  - Correctable endocrine disorders and other medical conditions have been ruled out, or are under successful treatment; AND
  - Medications that may contribute to the patient's obesity, such as antipsychotic medications, have been identified; AND
  - Patient has been compliant with active participation in a non-surgical weight reduction regimen for 6 or more consecutive months during the past 12 months; AND
  - Recommended strategies to address identified personal barriers to making and continuing needed life changes have been implemented;

  AND
- Patient has completed a surgical preparatory program. The surgical preparatory program's notes must document that the patient has been informed of **BOTH** of the following:
  - Required appointments with the surgery team the patient will need to attend before and after surgery; AND
  - Life changes patient must make and continue to make, including diet and exercise programs before and after surgery.

II. Patient Selection Criteria: Reoperation

- Revision bariatric surgery **OR** conversion of one type of bariatric surgery to a different procedure may be considered **MEDICALLY NECESSARY AND APPROPRIATE** using one of the procedures identified in section ~~II~~ III as medically necessary, for **EITHER** of the following indications:
  - Treatment of surgical complications or technical failures following the original bariatric surgery (e.g., staple line failure, band migration or slippage, pouch dilation, narrowing or constriction of the stoma); **OR**
  - Inadequate weight loss following the original surgery when **ALL** the following criteria are met:
    - At least two (2) years have elapsed since the original bariatric surgery; AND
    - Patient has been and continues to be compliant with the required appointments with the surgery team and the required life changes including diet and exercise recommended by the surgery team from the time of surgery up to the present time without any period of non-compliance; AND
    - Patient currently has a BMI ≥ 40 kg/m2 OR a BMI of 35 kg/m2 to < 40 kg/m2 with an obesity related comorbid condition as described in section I; AND
    - Evaluation by a mental health professional indicates any barriers to successful reoperation have been identified and addressed.

- Revision or conversion surgery is considered **NOT MEDICALLY NECESSARY** when performed for inadequate weight loss due to documentation of individual noncompliance with prescribed postoperative nutrition and exercise.

III. Surgical Procedures

- The following surgical procedures may be considered **MEDICALLY NECESSARY AND APPROPRIATE** in the treatment of morbid obesity when the previous patient selection criteria in section I have been met:
  - Open gastric bypass using a Roux-en-Y anastomosis with an alimentary or Roux limb of ≤ 150 cm
  - Laparoscopic gastric bypass using a Roux-en-Y anastomosis
  - Open or laparoscopic sleeve gastrectomy
  - Open or laparoscopic biliopancreatic diversion (i.e., Scopinaro procedure) with duodenal switch
  - Laparoscopic adjustable gastric banding, (i.e., Lap-Band® and REALIZE Band)

- Any other surgical or minimally invasive procedure is considered **EXPERIMENTAL/INVESTIGATIVE** as a treatment of morbid obesity including but not limited to the following due to the lack of evidence demonstrating an impact on improved health outcomes:
  - Open or laparoscopic vertical banded gastroplasty
  - Open adjustable gastric banding
  - Gastric bypass using a Billroth II type of anastomosis known as the mini-gastric bypass /one anastomosis gastric bypass (OAGB)
  - Biliopancreatic diversion (i.e., the Scopinaro procedure) without duodenal switch
  - Long limb gastric bypass procedure (i.e., > 150 cm)
  - Single anastomosis duodenal switch (i.e., stomach intestinal pylorus-sparing [SIPS] or single anastomosis duodenoileal bypass with sleeve gastrectomy [SADI-S])
  - Laparoscopic gastric plication
  - Bariatric surgery (any procedure) for patients with a BMI < 35 kg/m2 including but not limited to solely as a cure for type 2 diabetes mellitus
  - Endoluminal (also called endosurgical, endoscopic, sclerosing endotherapy or natural orifice transluminal endoscopic) procedure as a primary bariatric procedure or as a revision procedure by any method including but not limited to:
    - Aspiration therapy device (e.g., AspireAssist® Weight Loss Therapy System)
    - Duodenal-jejunal sleeve
    - Intragastric balloon therapy (e.g., Obalon, Orbera®, ReShape™ Duo systems)
    - Primary Obesity Surgery, Endoluminal (POSE)
    - StomaphyX™
    - Transpyloric Shuttle

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 be submitted:

1. **Initial Procedure**
   Documentation requirements described in Patient Selection criteria (section I) must be included in the prior authorization.

2. **Reoperation Procedure**
   - Date of previous bariatric surgery or surgeries;; **AND**
   - Initial procedure(s) performed; **AND**
   - One of the following:
     - Description of surgical complication(s) or technical failure;; OR
     - If reoperation due to Inadequate weight loss, clinic notes from the past 2 years including **ALL** of the following:
       - Patient's current BMI; **AND**
       - Obesity-related comorbid conditions ~~if present~~; **AND**
       - Record of psychological evaluation for reoperation **AND**
       - Copy of the surgery team's standard required appointments after surgery including and documentation of the following at each visit:
         - Patient's weight,
         - Patient's eating and exercise habits;
         - Progress toward achieving life changes the patient was instructed to make.

- **Alpha-1 Proteinase Inhibitors, II-206**

I. **Initial Review for Alpha-1 Proteinase Inhibitor (Prolastin®-C)**

Use of alpha-1 proteinase inhibitor (Prolastin®-C) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Age 18 years or older; **AND**
- Diagnosis of alpha-1-antitrypsin (AAT) deficiency with ONE of the following high-risk phenotypes:
  - PiZZ; or
  - PiZ (null); or
  - Pi (null, null);

  AND
- Serum concentration of AAT is ≤11 µM/L (equivalent to ≤80 mg/dL by immunodiffusion; or ≤57 mg/dL by nephelometry); **AND**
- Clinical evidence of panacinar emphysema; **AND**
- ONE of the following:
  - Moderate airflow obstruction is evidenced by forced expiratory volume at one second (FEV_1) of 30-65% of predicted value, prior to initiation of therapy; or
  - Patient has a rapid decline in lung function as measured by a change in FEV_1 >120 mL/year;

  AND
- Never or ex-smoker; **AND**
- Currently receiving standard therapy for COPD (eg, bronchodilator with beta agonists or anticholinergic agent; inhaled corticosteroid); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see table 2 below); **AND**
- For commercial health plan members only, the alpha-1 proteinase inhibitor is administered in accordance with site of service criteria (see policy XI-06).

II. Initial Review for Alpha-1 Proteinase Inhibitors (Aralast NP®, Glassia®, Zemaira®)

Use of alpha-1 proteinase inhibitor (Aralast NP®, Glassia®, Zemaira®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Initial review criteria outlined in section I are met; **AND**
- ONE of the following:
  - Previously tried and failed Prolastin®-C; or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to Prolastin®-C;

  AND
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement.)

III. Renewal Review for Alpha-1 Proteinase Inhibitors (Aralast NP®, Glassia®, Prolastin®-C, Zemaira®)

Use of an alpha-1 proteinase inhibitor may be considered **MEDICALLY NECESSARY AND APPROPRIATE** for retreatment in adult patients who meet **ALL** of the following:

- Previously approved for the requested alpha-1 proteinase inhibitor through the initial review process; **AND**
- Continue to meet criteria for initial infusion; **AND**
- Non-smoker or continues to be an ex-smoker; **AND**
- Disease response with treatment based on one or both of the following:

- Elevation of AAT levels above baseline; and/or
- Decreased rate of loss of lung function as measured by percent predicted FEV_1;

AND

- Currently receiving standard therapy for COPD (eg, bronchodilator, inhaled corticosteroid; PDE4 inhibitor, antibiotics, mucolytics/antioxidants); **AND**
- No FDA labeled contraindications to therapy (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the indication (see table 2 below); **AND**
- For commercial health plan members only, the alpha-1 proteinase inhibitor is administered in accordance with site of service criteria (see policy XI-06).

IV. Experimental/Investigative Uses

All other uses of alpha-1 proteinase inhibitors 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
Aralast NP	Immunoglobulin A (IgA) deficient patients with antibodies against IgA
Glassia	IgA deficient patients with antibodies against IgA History of anaphylaxis or other severe systemic reaction, to alpha-1protease inhibitor products
Prolastin-C	IgA deficient patients with antibodies against IgA History of anaphylaxis or other severe systemic reaction, to alpha-1protease inhibitor products
Zemaira	IgA deficient patients with antibodies against IgA, due to risk of hypersensitivity History of anaphylaxis or other severe systemic reaction, to alpha-1protease inhibitor products

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Alpha-1-antitrypsin (AAT) deficiency	60 mg/kg by IV infusion administered once every 7 days (weekly)

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 be submitted:

Initial Review

1. Clinical notes confirming protein phenotype and FEV_1 results.
2. Current COPD treatment regimen.
3. For commercial health plan members only, the site of service for alpha-1 proteinase inhibitor administration is specified, including CMS place of service code (see policy XI-06). If the alpha-1 proteinase inhibitor is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
4. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval of alpha-1 proteinase inhibitor therapy through the initial review process.
2. Documentation supporting positive clinical response or reduction of severity from baseline (ie, change in FEV_1 or AAT levels).
3. Clinical notes describing current and past treatments for COPD, including response to the treatments.
4. For commercial health plan members only, the site of service for alpha-1 proteinase inhibitor administration is specified, including CMS place of service code (see policy XI-06). If the alpha-1 proteinase inhibitor is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **Intravenous Enzyme Replacement Therapy for Gaucher Disease, II-214**

I. Initial Review for Velaglucerase Alfa (Vpriv®)

Velaglucerase alfa (Vpriv®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Diagnosis of Gaucher disease confirmed by **ONE** of the following:
  - Deficiency of glucocerebrosidase activity in peripheral blood leukocytes or fibroblasts; or
  - Genetic testing confirms pathogenic mutations in the glucocerebrosidase gene;

  AND
- Classified as type 1 or type 3 Gaucher disease; **AND**
- ONE or more symptoms or physical findings attributable to Gaucher disease, such as:
  - Skeletal disease; or
  - Hepatomegaly; or
  - Splenomegaly; or
  - Anemia; or
  - Thrombocytopenia;

  AND
- Used as monotherapy; **AND**
- No FDA labeled contraindications to the requested agent (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the labeled indication or is supported in literature for additional indications (see table 2 below); **AND**
- For commercial health plan members only, the requested agent is administered in accordance with site of

service criteria (see policy XI-06).

II. Initial Review for Imiglucerase (Cerezyme®) and Taliglucerase Alfa (Elelyso®)

Imiglucerase (Cerezyme®) or taliglucerase alfa (Elelyso®) may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Initial review criteria outlined in section I are met; **AND**
- ONE of the following:
  - Previously tried and failed velaglucerase alfa (Vpriv®); or
  - Documented intolerance, FDA labeled contraindication, or hypersensitivity to velaglucerase alfa (Vpriv®);

  AND
- For commercial health plan members only, step therapy supplement criteria may apply for select conditions (see policy II-242: Step Therapy Supplement).

III. Renewal Review for Imiglucerase (Cerezyme®), Taliglucerase Alfa (Elelyso®), and Velaglucerase Alfa (Vpriv®)

Imiglucerase, taliglucerase alfa, or velaglucerase alfa may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:

- Previously approved for the requested agent through the initial review process; **AND**
- Demonstrated positive clinical response to the requested agent (e.g., improvement in symptoms, reduction in size of liver or spleen, improvement in hemoglobin/anemia, improvement in skeletal disease, improvement in platelet counts); **AND**
- Used as monotherapy; **AND**
- No FDA labeled contraindications to the requested agent (see table 1 below); **AND**
- The dose is within the FDA labeled dose for the labeled indication or is supported in literature for additional indications (see table 2 below); **AND**
- For commercial health plan members only, the requested agent is administered in accordance with site of service criteria (see policy XI-06).

IV. Experimental/Investigative Uses

All other uses of imiglucerase, taliglucerase alfa, or velaglucerase alfa are considered **EXPERIMENTAL/INVESTIGATIVE**, including but not limited to treatment of type 2 Gaucher disease, due to the lack of evidence demonstrating an impact on improved health outcomes.

Table. FDA-Labeled Contraindications

Agent	FDA Labeled Contraindications
Imiglucerase	None
Taliglucerase alfa	None
Velaglucerase alfa	None

Table 2. Dosing

NOTE: See documentation submission requirements below if the requested dose is higher or more frequent than the dosing criteria provided in this table.

FDA Labeled Indications	Dosing
Imiglucerase – Gaucher disease	2.5 Units/kg 3 times a week to 60 Units/kg once every 2 weeks
Taliglucerase alfa – Gaucher disease	Treatment-naïve patients: 60 Units/kg administered every other week Patients switching from imiglucerase: Begin taliglucerase alfa at previous imiglucerase dose and administer every other week
Velaglucerase alfa – Gaucher disease	Treatment-naïve patients: 60 Units/kg administered every other week Patients switching from imiglucerase: Begin velaglucerase alfa at previous imiglucerase dose 2 weeks after last imiglucerase dose

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. Laboratory documentation confirming diagnosis of Gaucher disease.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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.
4. For commercial health plan members only, the site of service for drug administration is specified, including CMS place of service code (see policy XI-06). If the requested agent is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.
5. For commercial health plan members only, when step therapy requirements apply for the requested indication, documentation for one or more of the step therapy supplement criteria MUST be provided (see policy II-242).

Renewal Review

1. Documentation of prior approval for the requested agent through the initial review process.
2. Documentation supporting positive clinical response.
3. The dose being requested. If the requested dose is higher or more frequent than the dosing guidelines 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.
4. For commercial health plan members only, the site of service for drug administration is specified, including CMS place of service code (see policy XI-06). If the requested agent is administered in a hospital outpatient facility, a clear explanation for the medical necessity of the site of service MUST be submitted, including documentation for one or more of the site of service criteria provided in policy XI-06.

- **Genetic Cancer Susceptibility Panels, VI-56**
  Note: Testing for hereditary breast and ovarian cancer syndrome (*BRCA1* and *BRCA2* genes) including related panel testing is not addressed this policy. Please refer to policy VI-16: Genetic Testing for Hereditary Breast and/or Ovarian Cancer.

I. Genetic Counseling

Multigene cancer susceptibility panel testing may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria for genetic counseling are met along with criteria in section II:

- 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*;
    OR
  - An American Board of Medical Genetics or American Board of Genetic Counseling certified or certification eligible Genetic Counselor who has no financial relationship with the testing laboratory*; **OR**
  - 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*; **OR**
  - Board certified or board eligible medical specialist who is trained in the treatment of the genetic condition that is being tested, 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 or parent/guardian of individual:
    - When clinically appropriate, options for surveillance and risk reduction (e.g., reproductive decision-making, lifestyle, preventive measures) 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 physical and emotional risks associated with the 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 the laboratory test itself.

II. Multigene Cancer Susceptibility Panels

Multigene cancer susceptibility panels may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when criteria in Section I and **ALL** of the following are met:

- The genetic disorder is associated with one or more cancers; **AND**
- The risk of cancer from the genetic disorder cannot be identified through biochemical or other testing; **AND**
- The panel is limited to genes that have proven utility for clinical management of the specific cancer or cancer syndrome in question; **AND**
- Results of testing will impact the medical management of the individual (e.g., increased screening or surveillance); **AND**
- No previous germline cancer susceptibility testing or results of previous testing were incomplete.

III. Experimental/Investigative Testing

Multigene cancer susceptibility panels are considered **EXPERIMENTAL/INVESTIGATIVE** for all other indications, including but not limited to the following, due to a lack of clinical evidence demonstrating an impact on improved health outcomes:

- Panel includes genes for which there is no proven utility for clinical management of a specific cancer or cancer syndrome. These include but are not limited to:
  - CancerNext®
  - ColoNext®
  - Color Hereditary Cancer Test
  - Counsyl Reliant™ Cancer Screen
  - CustomNext-Cancer®
  - CustomNext + RNA: Lynch (MLH1, MSH2, MSH6, PMS2)
  - genTrue™ Hereditary Cancer Test
  - iGene Cancer Panel
  - OncoGeneDx Comprehensive Cancer Panel
  - OncoGeneDx High/Moderate Risk Panel
  - University of Washington ColoSeq™ Lynch and Polyposis Gene Panel
  - RenalNext™
  - +RNAinsight for BRCA1/2
  - +RNAinsight for BreastNext
  - +RNAinsight for CancerNext
  - +RNAinsight for ColoNext
  - +RNAinsight for GYNPlus
  - +RNAinsight for OvaNext
  - +RNAinsight for PALB2
  - +RNAinsight for ProstateNext
  - VistaSeq Hereditary Cancer Panel
- Testing performed in the absence of pretest genetic counseling by a cancer genetics professional independent of the laboratory performing the test
- Panel is offered as a direct access (also known as direct to consumer) test
- Panel testing in the general population as a screening tool
- All other uses of genetic cancer susceptibility panel testing which do not meet criteria as stated above

- **Panniculectomy/ Excision of Redundant Skin or Tissue, IV-24**

NOTE:

- The scope of this policy does not address primary circumcision of newborns or infants.
- Coverage may be subject to legislative mandates, including but not limited to the following, which apply prior to the policy statements:
  - Federal Women's Health and Cancer Rights Act (WHCRA)
  - Minnesota Statute 62A.25 Reconstructive Surgery

I. Panniculectomy

- Panniculectomy with or without abdominoplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when **ALL** of the following criteria are met:
  - The pannus/panniculus extends at or below the level of the symphysis pubis; **AND**
  - The treating physician has documented that the pannus/panniculus is associated with:

- Chronic or recurrent infection, intertrigo, or skin necrosis refractory to at least three months of medical management (e.g. antifungal, antibacterial, and moisture-absorbing agents; supportive garments, topically-applied skin barriers); **OR**
- Chronic or recurrent ulcerations, accompanied by skin deterioration, that are nonresponsive to aggressive wound management;

AND

- When the panniculectomy is associated with significant weight loss, weight has remained stable for a minimum of six months.

- Panniculectomy with or without abdominoplasty may be considered **MEDICALLY NECESSARY AND APPROPRIATE** as an adjunct to a medically necessary procedure when needed for exposure to improve surgical access or wound healing following surgery.
- The following procedures are considered COSMETIC as they are performed primarily to enhance or otherwise alter a physical appearance without correcting or improving a physiological function:
  - Panniculectomy with or without abdominoplasty not meeting the medical necessity criteria in the policy statements directly above;
  - Abdominoplasty;
  - Nonfunctional procedures performed in association with a medically necessary panniculectomy (e.g., transposition of the umbilicus, undermining to the costal margin, lateral contouring imbrications, lipectomy);
  - Repair of diastasis recti.

II. <u>Excision of Redundant Skin or Tissue of Other Anatomical Areas</u>

- Excision of redundant skin or tissue of other anatomical areas including but not limited to the upper extremities (e.g., brachioplasty), lower extremities, buttocks, or genitalia may be considered **MEDICALLY NECESSARY AND APPROPRIATE** when at least **ONE** of the following are met:
  - The treating physician has documented that the redundant skin is associated with:
    - Chronic or recurrent infection, intertrigo, or skin necrosis refractory to at least three months of medical management (e.g., antifungal, antibacterial, and moisture-absorbing agents, supportive garments, topically-applied skin barriers); **OR**
    - Chronic or recurrent ulcerations, accompanied by skin deterioration, that are nonresponsive to aggressive wound management; **OR**
    - Biopsy or removal of a premalignant or malignant skin lesion.
- Excision of redundant skin or tissue performed primarily to enhance or otherwise alter physical appearance is considered **COSMETIC.**

- **Mastopexy, IV-33**

NOTE:

- The policy does NOT address Gender Affirming Procedures for Gender Dysphoria (IV-123)
- Coverage may be subject to legislative mandates, including but not limited to the following, which apply prior to the policy statements:
  - Federal Women's Health and Cancer Rights Act (WHCRA)
  - Minnesota Statute 62A.25 Reconstructive Surgery

Coverage

In accordance with the mandates listed above, mastopexy is covered when performed as a breast reconstruction procedure following or in conjunction with mastectomy or breast-conserving surgery due to a diagnosis of breast cancer. This includes mastopexy for treatment of physical complications of the mastectomy, including lymphedema.

Policy Position
Mastopexy in all other situations is considered **COSMETIC** as it is performed primarily to enhance or otherwise alter physical appearance except when performed as part of a covered breast reconstructive service.

Policies Inactivated

- **Quantitative Electroencephalogram (QEEG) or Brain Mapping for Mental Health or Substance Related Disorders, X-26**

Policies Delegated to eviCore

- **Gene Expression Profiling and Protein Biomarkers for Prostate Cancer Management, VI-57**
  For applicable clinical criteria, see the following eviCore clinical guideline(s):
  - Lab Management Program Guideline
    - MOL.TS.294.A Decipher Prostate Cancer Classifier
    - MOL.TS.295.A Oncotype DX for Prostate Cancer
    - MOL.TS.297.A Prolaris
    - MOL.TS.296.A ProMark Proteomic Prognostic Test

- **Facet Arthroplasty, IV-110**
  For applicable clinical criteria, see the following eviCore clinical guideline:
  - Spine Surgery Guidelines
    - CMM-609.6 Lumbar Fusion (Arthrodesis) Non-Indications