Mass General Brigham
Health Plan

Enzyme and Metabolic Disorder Therapies
Effective 01/02/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

No PA	Require PA
Ammonul® # (sodium phenylacetate/sodium benzoate) Buphenyl® # (sodium phenylbutyrate powder, tablet) Creon® DR (pancrelipase) Pancreaze® DR (pancrelipase) † Pertzye® DR (pancrelipase) Viokace® (pancrelipase) Zenpep® DR (pancrelipase)	Aldurazyme® (laronidase) MB Carbaglu® (carglumic acid)* PD BP Cerdelga® (eliglustat) Cerezyme® (imiglucerase) MB Dojolvi® (triheptanoin) Elaprase® (idursulfase) MB Elelyso® (taliglucerase alfa) MB Elfabrio® (pegunigalsidase alfa-iwxj) DUAL Fabrazyme® (agalsidase beta) Galafold® (migalastat) Joenja® (leniolisib) Kanuma® (sebelipase alfa) MB Kuvan® (sapropterin)* Lamzede® (velmanase alfa-tycv) MB Lumizyme® (alglucosidase alfa) MB Mepsevii® (vestronidase alfa-vjbk) MB Naglazyme® (galsulfase) MB Nexviazyme® (avalglucosidase alfa-ngpt) MB Nulibry® (fosdenopterin) MB Olpruva® (sodium phenylbutyrate pellets for suspension) Palynziq® (pegvaliase-pqpz) DUAL Pheburane® (sodium phenylbutyrate granules) Pyrukynd® (mitapivat) Revcovi® (elapegademase-lvlr) DUAL Ryplazim (plasminogen, human-tvmh) DUAL

	Strensiq® (asfotase alfa) Sucraid® (sacrosidase)* † Vijoice® (alpelisib) Vimizim® (elosulfase alfa) MB Vpriv® (velaglucerase alfa) MB Xenpozyme (olipudase alfa-rpcp) MB Xuriden® (uridine triacetate) † Zavesca® (miglustat)* BP

* A-rated generic available. Both brand and A-rated generic require PA.
†Non-rebate product
This designates a brand-name drug with FDA "A"-rated generic equivalents. Prior authorization is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
BP - Brand Preferred over generic equivalents. In general, requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
PD - preferred drug. In general, requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. **Please note, for Enzyme and Metabolic Disorder Therapies, a trial with Carbaglu is not required prior to approval of a non-preferred agent.**
MB - This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy
DUAL – Drug is available through both pharmacy and medical benefits

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.
OR
Authorization will be granted when all the following criteria has been met:

Aldurazyme (laronidase)
ALL of the following:
1. Diagnosis of Mucopolysaccharidosis I (MPS I)
2. Results from genetic testing showing mutations in IDUA gene or an enzyme assay test showing reduced lysosomal alpha-L-iduronidase activity in peripheral blood leukocytes, plasma, or cultured fibroblasts
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Carbaglu (carglumic acid)BP
ONE of the following:
1. Diagnosis of NAGS deficiency
    a. Results from genetic test or an enzyme assay test (i.e., liver biopsy) supporting the diagnosis
    b. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
    c. Appropriate dosing
2. Diagnosis of hyperammonemia due to propionic aciduria (PA) or methylmalonic aciduria (MMA)
    a. Results from genetic testing, medical records, or lab results supporting the diagnosis
    b. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided

c. Elevated ammonia levels >60 µmol/L
d. Appropriate dosing

3. Diagnosis of *acute hyperammonemia in isovaleric aciduria (off-label)*
    a. Medical records and/or laboratory testing results supporting the diagnosis of IVA
    b. Abnormally elevated baseline ammonia levels (e.g., >60 µmol/L)
    c. Appropriate dosing (see Availability and Dosage table below)

Cerdelga (eliglustat)
ALL of the following:

1. Diagnosis of Gaucher disease (Type I)
2. Member is ≥18 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Results from an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase
5. Documentation showing that member is NOT currently receiving enzyme replacement therapy (ERT) (i.e., Cerezyme® [imiglucerase], Vpriv® [velaglucerase alfa] or Elelyso® [taliglucerase alfa])

Cerezyme (imiglucerase)
Vpriv (velaglucerase alfa*)*
ALL of the following:

1. Diagnosis of Gaucher disease (Type I)
2. Results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Dojolvi (triheptanoin)
ALL of the following:

1. Diagnosis of long chain fatty acid oxidation disorder (LC-FAOD)
2. Results from genetic testing or molecular analysis to confirm diagnosis (e.g., CPT I or II, LCHAD, TFP, VLCAD deficiency)
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Documentation of a trial with a diet consisting of low-fat, high-carbohydrates, and avoidance of fasting
5. Member's current caloric intake *(use to verify correct dosing)*

Elaprase (idursulfase)
ALL of the following:

1. Diagnosis of Hunter Syndrome (Mucopolysaccharidosis II)
2. Results from genetic testing confirming mutation in IDS gene or iduronate-2-sulfatase assay test showing reduced or absent activity in the serum, white blood cells, or fibroblasts
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Elelyso (taliglucerase alfa)
ALL of the following:

1. Diagnosis of Gaucher disease (Type I)
2. Results from genetic test confirming mutation in GBA gene or an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member is ≥ 4 years of age
5. Member's current weight *(use to verify correct dosing)*

Elfabrio (pegunigalsidase alfa-iwxj)
Fabrazyme (agalsidase beta)
ALL of the following:
1. Diagnosis of Fabry disease
2. One of the following confirming diagnosis:
    a. Results from an enzyme assay test showing reduced or absent α-GAL enzyme activity in plasma, leukocytes, tears, or biopsied tissue
    b. Genetic testing confirming mutation in GAL gene
    c. Biomarker demonstrating an increase in Gb3 concentration
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*
5. For Elfabrio® (pegunigalsidase alfa-iwxj), inadequate response, adverse reaction, or contraindication to Fabrazyme® (agalsidase beta)

Galafold (migalastat)
ALL of the following:
1. Diagnosis of Fabry disease
2. Member is ≥18 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Results from an enzyme assay test showing reduced or absent α-galactosidase A (α-GAL) enzyme activity in plasma, leukocytes, tears, or biopsied tissue
5. Member has GLA variants (mutations) which are amenable to treatment with migalastat (based on genetics consult notes)
6. Requested quantity is ≤15 units/30 days (0.5 units/day)

Joenja (leniolisib)
ALL of the following:
1. Diagnosis of APDS
2. Member is ≥ 12 years of age
3. Member weight is ≥ 45 kg
4. Prescriber is a specialist (e.g., pediatrician, hematologist/oncologist, or allergist/immunologist) or consult notes from a specialist are provided
5. Results from genetic testing confirming mutation in the PIK3CD or PIK3R1 genes
6. Appropriate dosing

Kanuma (sebelipase alfa)
ALL of the following:
1. Diagnosis of lysosomal acid lipase deficiency

2. **ONE** of the following:
    a. Lab assay documenting low lysosomal acid lipase activity
    b. Genetic testing confirming full or partial loss of LAL gene
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Kuvan (sapropterin)
ALL of the following:
1. Diagnosis of phenylketonuria
2. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
3. Documentation that medication will be used in conjunction with a phenylalanine-restricted diet
4. Member's current weight *(use to verify correct dosing)*

Lamzede (velmanase alfa-tycv)
ALL of the following:
1. Diagnosis of alpha-mannosidosis
2. Member is ≥ 3 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided
4. Copy of a genetic test confirming diagnosis of alpha-mannosidosis (e.g., mutation of MAN2B1 gene)
5. Baseline measurements for **ALL** of the following tests:
    a. serum oligosaccharides
    b. forced vital capacity
    c. **ONE** of the following motor function tests:
        i. 3-minute stair climb test
        ii. 6-minute walk test
6. Member's current weight *(use to verify correct dosing)*

Lumizyme (alglucosidase alfa)*
ALL of the following:
1. Diagnosis of Pompe Disease
2. **ONE** of the following confirming diagnosis:
    a. Results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts
    b. lymphocyte testing
    c. blood spot assay
    d. genetic testing confirming mutation in GAA gene
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

* Lumizyme® and Nexviazyme® should not be used concurrently

Mepsevii (vestronidase alfa-vjbk)
ALL of the following:
1. Diagnosis of Mucopolysaccharidosis VII (MPS VII, Sly syndrome)
2. Results from genetic testing showing mutations in the beta glucuronidase gene

3. Prescriber is a specialist in genetic or metabolic diseases or provides documentation of a consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Naglazyme (galsulfase)
ALL of the following:
1. Diagnosis of Mucopolysaccharidosis VI (MPS VI)
2. Results from an enzyme assay test showing reduced arylsulfatase B (ASB) enzyme activity in leukocytes or fibroblasts along with elevated urine glycosaminoglycan (GAG) levels
3. Prescriber is a specialist in genetic or metabolic diseases or provides documentation of a consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Nexviazyme (avalglucosidase alfa-ngpt) *
ALL of the following:
1. Diagnosis of late-onset Pompe Disease
2. **ONE** of the following confirming diagnosis:
    a. results from GAA assay test showing reduced or absent activity from cultured skin fibroblasts
    b. lymphocyte testing
    c. blood spot assay
    d. genetic testing confirming mutation in GAA gene
3. Member is ≥ one year of age
4. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided.
5. Member's current weight *(use to verify correct dosing)*
6. **If reviewing under Pharmacy Benefit:** For members weighing < 30 kg, contraindication to Lumizyme®

* Lumizyme® and Nexviazyme® should not be used concurrently

Nulibry (fosdenopterin)
ALL of the following:
1. Diagnosis of molybdenum cofactor deficiency (MoCD) Type A confirmed by genetic testing
2. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
3. Appropriate dosing
4. Member's current weight *(use to verify correct dosing)*

Olpruva (sodium phenylbutyrate pellets for suspension)
1. Diagnosis of urea cycle disorder (UCD)
2. Results from genetic test or an enzyme assay test (liver biopsy, fibroblast from skin biopsy, or red blood cells) supporting the diagnosis
3. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided
4. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
    a. sodium phenylbutyrate powder
    b. sodium phenylbutyrate tablet
5. Inadequate response, adverse reaction, or contraindication to Pheburane® (sodium phenylbutyrate granules)
6. Appropriate dosing

Palynziq (pegvaliase-pqpz)
ALL of the following:

1. Diagnosis of phenylketonuria
2. Member is ≥ 18 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Blood phenylalanine concentrations >600 micromol/L
5. The medication will be used in conjunction with a phenylalanine-restricted diet
6. **If reviewing under Pharmacy Benefit**: Physician attestation of inadequate response, adverse reaction, or contraindication to sapropterin

Pheburane (sodium phenylbutyrate granules)
ALL of the following:

1. Diagnosis of urea cycle disorder (UCD)
2. Results from genetic test or an enzyme assay test (liver biopsy, fibroblast from skin biopsy, or red blood cells) supporting the diagnosis
3. Prescriber is a specialist in genetic or metabolic diseases or consult notes from a specialist are provided
4. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following**:*
    a. sodium phenylbutyrate powder
    b. sodium phenylbutyrate tablet
5. Appropriate dosing

* Requests noting inability to tolerate sodium phenylbutyrate powder or tablet formulations due to unpleasant taste will be evaluated on a case-by-case basis, taking into consideration whether a masking agent (e.g., chocolate syrup or peanut butter) or the taste-masked pellet formulation was tried.

Pyrukynd (mitapivat)
ALL of the following:

1. Diagnosis of hemolytic anemia with pyruvate kinase deficiency
2. Member is ≥ 18 years of age
3. Results from genetic testing confirming mutation in PKLR gene or lab testing showing reduced or absent activity of pyruvate kinase
4. Prescriber is a specialist in genetic diseases, hematology, or metabolic diseases or consultation notes from a specialist are provided
5. Hb ≤ 10 g/dL (dated within the last 60 days)
6. Requested quantity is ≤ 2 units/day

Revcovi (elapegademase-lvlr)
ALL of the following:

1. Diagnosis of adenosine deaminase severe combined immunodeficiency (ADA-SCID)
2. Laboratory results documenting **ONE** of the following:
    a. Absent ADA enzymatic activity in lysed erythrocytes
    b. Elevated levels of adenosine and deoxyadenosine in the urine and plasma
    c. A marked increase in deoxyadenosine triphosphate (dATP) levels in erythrocyte lysates
    d. A significant decrease in ATP concentration in red blood cells
    e. Absent or extremely low levels of N adenosylhomocysteine hydrolase in red blood cells

f. Severe T cell deficiency manifested by lymphopenia and poor T cell responses to mitogens and antigens
g. Absent thymic shadow on chest radiograph

3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Ryplazim (plasminogen, human-tvmh)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of PLGD type 1
2. History of lesions (external and/or internal) and symptoms consistent with a diagnosis of PLGD type 1 (e.g., ligneous conjunctivitis, ligneous gingivitis or gingival overgrowth, vision abnormalities, respiratory distress and/or obstruction, abnormal wound healing)
3. Baseline plasminogen activity level ≤45%
4. ONE of the following:
    a. Results from genetic testing showing mutations in PLG gene
    b. Member has plasminogen antigen levels ≤9 mg/dL
5. Requested dose is ≤ 6.6 mg/kg every two to four days

Strensiq (asfotase alfa)
ALL of the following:

1. Diagnosis of perinatal-onset, infantile-onset or juvenile-onset hypophosphatasia
2. Genetic testing confirming mutation in ALPL gene
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Sucraid (sacrosidase)
ALL of the following:

1. Diagnosis of congenital sucrase-isomaltase deficiency (CSID)
2. Results from small bowel biopsy or breath hydrogen test showing reduced or absent enzyme activity or sucrase breath test
3. Prescriber is a specialist in genetic or metabolic diseases, a gastroenterologist, or consultation notes from a specialist or gastroenterologist are provided
4. Member's current weight *(use to verify correct dosing)*

Vijoice (alpelisib)
ALL of the following:

1. Diagnosis of PROS with congenital or early childhood onset*
2. Member is ≥ 2 years of age
3. Overgrowth is sporadic and mosaic (i.e., patchy, irregular)
4. Results from genetic testing showing evidence of a mutation in the PIK3CA gene
5. Medical records documenting **ONE** of the following:
    a. Spectrum categorization defined as having at least **TWO** of the following:
        i. Adipose, muscle, nerve, or skeletal overgrowth
        ii. Capillary, venous, arteriovenous, or lymphatic vascular malformations
        iii. Epidermal nevus
    b. Isolated features defined as having **ONE** of the following:

i. Large isolated lymphatic malformation
ii. Isolated macrodactyly or overgrown splayed feet/hands, overgrown limbs
iii. Truncal adipose overgrowth
iv. Bilateral hemimegalencephaly/dysplastic megalencephaly/focal cortical dysplasia type 2
v. Epidermal nevus
vi. Seborrheic keratoses
vii. Benign lichenoid keratoses

6. Appropriate dosing

** The following are subtypes of PROS and are acceptable as meeting diagnosis criteria: CLAPO syndrome, CLOVES syndrome, diffuse capillary malformation with overgrowth (DCMO), dysplastic megalencephaly (DMEG), fibroadipose hyperplasia (FAH), fibroadipose overgrowth (FAO), hemihyperplasia multiple lipomatosis (HHML), fibro-adipose vascular anomaly (FAVA), facial infiltrating lipomatosis (FIL), HMEG, Klippel-Trenaunay syndrome (KTS), LON, macrodactyly, megalencephaly-capillary malformation syndrome (MCAP), muscular hemihyperplasia (HH)*

Vimizim (elosulfase alfa)
ALL of the following:

1. Diagnosis of Mucopolysaccharidosis IVA (Morquio A syndrome)
2. Member is ≥ 5 years of age
3. Results from an enzyme assay test showing reduced N-acetylgalactosamine-6-sulfatase activity in blood and/or skin cells
4. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
5. Member's current weight *(use to verify correct dosing)*

Xenpozyme (olipudase alfa-rpcp)
ALL of the following:

1. Diagnosis of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) type B, or ASMD type A/B
2. Prescriber is a specialist (e.g., medical geneticist or a specialist familiar with lysosomal storage disorders) or consultation notes from a specialist are provided
3. ONE of the following:
    a. For members ≥ 18 years of age, **BOTH** of the following:
        i. DLco ≤ 70% of predicted normal value
        ii. Spleen volume ≥ 6 MN
    b. For members < 18 years of age, spleen volume ≥ 5 MN
4. Member does **NOT** have acute or rapidly progressive neurologic abnormalities
5. BOTH of the following:
    a. Member does **NOT** require invasive ventilatory support
    b. Member does **NOT** require noninvasive ventilatory support while awake for > 12 hours a day
6. Member's current weight *(use to verify correct dosing)*
7. Appropriate dosing

Xuriden (uridine triacetate)
ALL of the following:

1. Diagnosis of hereditary orotic aciduria (HOA)
2. Genetic testing confirming mutation in UMPS gene

3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Member's current weight *(use to verify correct dosing)*

Zavesca (miglustat)[BP]
ALL of the following:
1. Diagnosis of Gaucher disease (Type I)
2. Member is ≥18 years of age
3. Prescriber is a specialist in genetic or metabolic diseases or consultation notes from a specialist are provided
4. Results from an enzyme assay test showing reduced activity of the enzyme glucocerebrosidase
5. Contraindication to enzyme replacement therapy (ERT) (e.g., hypersensitivity, allergy or poor venous access)

Continuation of Therapy
Dojolvi: Reauthorization by physician will infer a positive response to therapy and dosing is appropriate based on updated member's caloric intake.

Joenja: Reauthorization by prescriber must document positive response to therapy or clinical rationale for continued use.

Lamzede:
Prescriber provides documentation of **ONE** of the following:
1. Current tests (within the past 3 months) documenting positive response to therapy for **ALL** of the following tests:
    a. serum oligosaccharides
    b. forced vital capacity
    c. **ONE** of the following motor function tests:
        i. 3-minute stair climb test
        ii. 6-minute walk test
2. Medical necessity for continuing therapy (e.g., disease stabilization or a reduction in normal motor decline)

Ryplazim and **Nulibry**: Reauthorization will require physician documentation of a positive response to therapy or clinical rationale for continued use if dosing is appropriate based on updated member's weight where applicable.

Xenpozyme: Prescriber provides documentation of **BOTH** of the following:
1. Improvement from baseline in DLco and spleen volume
2. Updated member weight

Limitations
1. Initial approvals will be granted for the following:
    a. Dojolvi, Lamzede, Nulibry, Palynziq, Vijoice, Xenpozyme: 6 months
    b. Joenja: 12 weeks
    c. Ryplazim: 24 weeks
    d. All other agents: 1 year
2. Reauthorizations will be granted for the following:

a. Joenja: 24 weeks
b. Xenpozyme – improvement in DLco and spleen volume: 6 months
c. All other agents: 1 year

3. Members who are stable on Nulibry® (fosdenopterin) must meet both the initial and reauthorization criteria for approval.
4. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
5. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
6. The following quantity limits apply:

Galafold (migalastat)	15 units per 30 days
Pyrukynd (mitapivat)	60 units per 30 days

Appendix

Brand Preferred over Generic:

Requests for generic versions listed below require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent prior to approval:

- carglumic acid
- miglustat

References

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Review History

02/08/2023 - Reviewed and created for Feb P&T; matched MH UPPL. Created criteria to be in compliance with Masshealth unified formulary requirements (Effective 4/1/23).
05/10/23 – Reviewed and updated for P&T. Added new drug, Ryplazim® (plasminogen, human-tvmh), to policy. Added initial and reauthorization criteria for Xenpozyme for the treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. A noted was added for Fabrazyme to clarify that Gb3 may be referred to as GL-3. References updated. Effective 6/5/23
06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement from Palynziq and Nexviazyme for requests through MB. Effective 6/30/23
07/12/23 – Reviewed and updated for P&T. Added new drug, Lamzede, to policy requiring PA under MB. Brand preferred and mandatory generic language was added under Limitations. Effective 7/31/23
11/15/23 – Reviewed and updated for P&T. Policy update to restrict Nexviazyme to medical billing. Genetic testing requirement was removed from criteria for Kuvan and Palynziq. Effective 12/4/23
12/13/23 – Reviewed and updated for P&T. Elfabrio, Joenja, and Olpruva added to criteria requiring PA. Effective 1/2/24