Medical Policy Bulletin

Title:
Sebelipase alfa (Kanuma®)
Policy #:
MA08.078e

The Company makes decisions on coverage based on the Centers for Medicare and Medicaid Services (CMS) regulations and guidance, benefit plan documents and contracts, and the member's medical history and condition. If CMS does not have a position addressing a service, the Company makes decisions based on Company Policy Bulletins. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable. Although the Medicare Advantage Policy Bulletin is consistent with Medicare's regulations and guidance, the Company's payment methodology may differ from Medicare.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition. This decision is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Policy Bulletin document describes the status of CMS coverage, medical terminology, and/or benefit plan documents and contracts at the time the document was developed. This Policy Bulletin will be reviewed regularly and be updated as Medicare changes their regulations and guidance, scientific and medical literature becomes available, and/or the benefit plan documents and/or contracts are changed.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's Evidence of Coverage.

In the absence of coverage criteria from applicable Medicare statutes, regulations, NCDs, LCDs, CMS manuals, or other Medicare coverage documents, this policy uses internal coverage criteria developed by the Company in consideration of peer-reviewed medical literature, clinical practice guidelines, and/or regulatory status.

The Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member's medical needs and condition.

MEDICALLY NECESSARY

INFANTS WITH RAPIDLY PROGRESSIVE LYSOSOMAL ACID LIPASE (LAL) DEFICIENCY PRESENTING WITHIN THE FIRST 6 MONTHS OF LIFE
Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for infants with rapidly progressive lysosomal acid lipase (LAL) deficiency presenting within the first 6 months of life when **all** the following criteria, including Dosing and Frequency Requirements, are met:

- Diagnosis of LAL deficiency is confirmed by **either** of the following:
  - Confirmation of the absence or deficiency of LAL resulting from dried blood spot (DBS) testing
  - Confirmation of molecular genetic testing that reveals pathogenic variation(s) in the lipase A, lysosomal acid type (LIPA) gene, which results in reduction of functionality of LAL enzyme activity
- Documented presence of clinical signs and symptoms of the disease (e.g., diarrhea, vomiting, marked failure to thrive [e.g., weight decreasing across two or more major centiles on a standard World Health Organization {WHO} weight-for-age {WFA} chart; body weight below the 10th centile on a standard WHO WFA chart and no weight gain during the 2 weeks before screening; loss of greater than 5 percent of birth weight after 2 weeks of age], abdominal distension, hepatomegaly, splenomegaly, rapidly progressive liver failure, adrenal calcifications, anemia)

Dosing and Frequency Requirements

The following dosing and frequency information, and definitions of suboptimal clinical responses, were taken from the Prescribing Information for this product and specific reliable evidence including peer-reviewed literature:

Infants with rapidly progressive LAL deficiency presenting within the first six months of life: 1 mg/kg intravenously (IV) once weekly. If optimal clinical response is not achieved, increase to 3 mg/kg once weekly. For continued suboptimal clinical response on 3 mg/kg once weekly dosage, further increase the dosage to 5 mg/kg once weekly.

A suboptimal clinical response within the first 3 months of treatment is defined as **all** of the following:

- Absence of other potential causes of any observed clinical manifestations
- Absence of missed infusions
- Absence of acute cholecystitis
- Absence of the initiation of a potentially hepatotoxic concomitant medication
- Absence of a concomitant illness that could cause any of the observed lack of clinical responsiveness to the drug
- **Two or more** of the following after receiving at least 4 infusions of the current dose:
    - Poor growth (i.e., failure to gain an average of 5 g/kg body weight per day **AND** the presence of either WHO weight-for-length or weight-for-height z score less than -2, or WHO length-for-age or height-for-age z score less than -2)
    - Albumin less than 3.5 g/dl
    - ALT more than twice the upper limit of normal (ULN)
    - Ongoing requirement for blood and/or platelet transfusion
    - Presence of anti-drug, anti-enzyme, or anti-uptake antibodies

A suboptimal clinical response after the first 3 months of treatment is defined as lack of improvement from a minimum of 3 assessments or failure to normalize within 12 months of treatment in **all** of the following:

- Absence of other potential causes of any observed clinical manifestations
- Absence of missed infusions
- Absence of acute cholecystitis
- Absence of the initiation of a potentially hepatotoxic concomitant medication
- Absence of a concomitant illness that could cause any of the observed lack of clinical responsiveness to the drug
- **One or more** of the following (not an all-inclusive list of the clinically important manifestations of LAL deficiency):
    - Decrease in weight-for-age crossing at least 2 major centiles
    - Albumin less than 3.5 g/dl
    - ALT more than twice the ULN
    - Persistent or worsening hepatomegaly, splenomegaly, or lymphadenopathy
    - Presence of anti-drug, anti-enzyme, or anti-uptake antibodies

PEDIATRIC AND ADULT INDIVIDUALS WITH LAL DEFICIENCY
Initial Therapy

Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for pediatric and adult individuals with lysosomal acid lipase (LAL) deficiency when **all** the following criteria, including Dosing and Frequency Requirements, are met:

- Diagnosis of LAL deficiency is confirmed by **either** of the following:
    - Confirmation of the absence or deficiency of LAL resulting from dried blood spot (DBS) testing
    - Confirmation of molecular genetic testing that reveals pathogenic variation(s) in the lipase A, lysosomal acid type (LIPA) gene, which results in reduction of functionality of LAL enzyme activity
- Documented presence of clinical signs and symptoms of the disease (e.g., hepatomegaly, dyslipidemia, increased serum transaminases [ALT, aspartate aminotransferase {AST}], evidence of advanced liver disease [i.e., cirrhosis, fibrosis, steatosis], histologically-confirmed disease recurrence in individuals with past liver or hematopoietic transplant more than 2 years prior)

Continuation Therapy

Sebelipase alfa (Kanuma) is considered medically necessary and, therefore, covered for continuation therapy of LAL deficiency in individuals who have improvement from baseline (for the initial request for continuation therapy), or maintenance of previous improvements, as evidenced by at least **two** of the following:

- Improvement in any **one** of the following symptoms:

    - For pediatric individuals: increase in growth and/or weight parameters (based on expected anthropometric parameters)
    - Decrease in diarrhea/vomiting (i.e., decrease in frequency and/or volume)
    - Improvement in liver volume (normal liver volume in liters is defined as 2.5 percent of body weight in kg)
    - Improvement in liver fat content (i.e., decrease of >5 percent in the liver fat content from baseline as measured by magnetic resonance imaging [MRI]; the normal fat content of the liver is considered to be <5 percent)
    - Improvement in liver histopathology (e.g., cirrhosis, fibrosis)
- Improvement in any **one** component of a lipid panels:
    - Improvement in low-density lipoprotein-cholesterol (LDL-c) (based on clinical comparisons with baseline and/or previous results)
    - Improvement in high-density lipoprotein-cholesterol (HDL-c) (based on clinical comparisons with baseline and/or previous results)
    - Improvement in triglycerides (TG) (based on clinical comparisons with baseline and/or previous results)
- Improvement in any **one** serum transaminases
    - Improvement in ALT (based on clinical comparisons with baseline and/or previous results)
    - Improvement in AST (based on clinical comparisons with baseline and/or previous results)

If the individual does not demonstrate continued improvement, or maintenance of previous improvement, from baseline in **two** of the above after 8 consecutive infusions, and is on a higher dosage of sebelipase alfa (Kanuma), then the dosage will be decreased to the previous dosage that demonstrated efficacy for the individual.

Dosing and Frequency Requirements

The following dosing and frequency information, and definitions of suboptimal clinical response/significant clinical progression, were taken from the Prescribing Information for this product and specific reliable evidence including peer-reviewed literature:

Pediatric and Adult Individuals with LAL Deficiency: 1 mg/kg IV once every other week. For individuals with a suboptimal clinical response or significant clinical progression, increase the dosage to 3 mg/kg once every other week.

A suboptimal clinical response is defined as **all** of the following after at least 8 consecutive infusions:

- Absence of other potential causes of any observed clinical manifestations (e.g., initiation of a potentially hepatotoxic concomitant medication in an individual with abnormal AST or ALT; missed infusions; development of viral or autoimmune hepatitis; development of another alternative etiology of liver disease)
- Presence of **one** of the following:
    - ALT or AST remain abnormal and either have not improved from baseline or have worsened from the previously achieved lowest value over the preceding 8 consecutive infusions
    - LDL-c or TG remain abnormal and either have not improved or have worsened over the preceding 8 consecutive infusions
    - The individual is <18 years of age at the time of the assessment and has a WFA z-score that is 2 standard deviations below the mean and either did not improve or worsened during the preceding 6 months and the individual did not miss more than 20 percent of infusions in the preceding 6 months

A significant clinical progression is defined as **all** of the following after at least 5 consecutive infusions:

- Absence of other potential causes of any observed clinical manifestations (e.g., initiation of a potentially hepatotoxic concomitant medication in an individual with abnormal AST or ALT; missed infusions; development of viral or autoimmune hepatitis; development of another alternative etiology of liver disease)
- Confirmed elevation of ALT or AST to >5x ULN and at least twice the highest pre-treatment value **AND** the presence of **one** of the following:
    - Increase of total bilirubin to >3x ULN and at least twice the highest pre-treatment value
    - Prolongation of prothrombin time (PT) 4 seconds or greater above baseline
    - Development or worsening of ascites
    - Development of encephalopathy

Subject to the terms and conditions of the applicable benefit contract, sebelipase alfa (Kanuma) is covered under the medical benefits of the Company's products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

The Company reserves the right to modify the Dosing and Frequency Requirements listed in this policy to ensure consistency with the most recently published recommendations for the use of sebelipase alfa (Kanuma). Changes to these guidelines are based on a consensus of information obtained from resources such as, but not limited to: the US Food and Drug Administration (FDA); Company-recognized authoritative pharmacology compendia; or published peer-reviewed clinical research. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for an amount of sebelipase alfa (Kanuma) outside of the Dosing and Frequency Requirements listed in this policy. For a list of Company-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.

Accurate member information is necessary for the Company to approve the requested dose and frequency of this drug. If the member's dose, frequency, or regimen changes (based on factors such as changes in member weight or incomplete therapeutic response), the provider must submit those changes to the Company for a new approval based on those changes as part of the utilization management activities. The Company reserves the right to conduct post-payment review and audit procedures for any claims submitted for sebelipase alfa (Kanuma).

NOT MEDICALLY NECESSARY

When molecular genetic testing reveals established benign variation(s) or wild-type genotype in the lipase A, lysosomal acid type (LIPA) gene, sebelipase alfa (Kanuma) is considered not medically necessary and, therefore, not covered because the available published peer-reviewed literature does not support its use in the treatment of this disease.

EXPERIMENTAL/INVESTIGATIONAL

All other uses for sebelipase alfa (Kanuma) are considered experimental/investigational and, therefore, not covered unless the indication is supported as an accepted off-label use, as defined in the Company medical policy on off-label coverage for prescription drugs and biologics.

When molecular genetic testing reveals likely pathogenic or variations of unknown significance (VUS) in the lipase A, lysosomal acid type (LIPA) gene, the use of sebelipase alfa (Kanuma) is considered experimental/investigational and, therefore, not covered because the safety and/or effectiveness of this service cannot be established by review of the available published peer-reviewed literature.

REQUIRED DOCUMENTATION

The individual's medical record must reflect the medical necessity for the care provided. These medical records may include, but are not limited to: records from the professional provider's office, hospital, nursing home, home health agencies, therapies, and test reports.

The Company may conduct reviews and audits of services to our members, regardless of the participation status of the provider. All documentation is to be available to the Company upon request. Failure to produce the requested information may result in a denial for the drug.

When coverage of sebelipase alfa (Kanuma) is requested outside of the Dosing and Frequency Requirements listed in this policy, the prescribing professional provider must supply documentation (i.e., published peer-reviewed literature) to the Company that supports this request.

Guidelines

There is no Medicare coverage determination addressing sebelipase alfa (Kanuma); therefore, the Company policy is applicable.

ADDITIONAL SERUM LABORATORY STUDIES

In certain instances of lysosomal acid lipase (LAL) deficiency, the following improvements in serum laboratory studies may need to be given addition considerational once the above continuation therapy medically necessary criteria have been reviewed:

- Improvement in gamma-glutamyl transferase (GGT) (based on clinical comparisons with baseline and/or previous results)
- Improvement in albumin level (based on clinical comparisons with baseline and/or previous results)
- Improvement in protein level (based on clinical comparisons with baseline and/or previous results)
- Improvement in total and conjugated bilirubin (based on clinical comparisons with baseline and/or previous results)
- Improvement in alkaline phosphatase (based on clinical comparisons with baseline and/or previous results)
- Improvement in lactate dehydrogenase (based on clinical comparisons with baseline and/or previous results)
- Improvement in hemoglobin (based on clinical comparisons with baseline and/or previous results)

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable Evidence of Coverage, sebelipase alfa (Kanuma) is covered under the medical benefits of the Company's Medicare Advantage products when the medical necessity criteria and Dosing and Frequency Requirements listed in this medical policy are met.

For Medicare Advantage members, certain drugs are available through either the member's medical benefit (Part B benefit) or pharmacy benefit (Part D benefit), depending on how the drug is prescribed, dispensed, or administered. This policy only addresses instances when sebelipase alfa (Kanuma) is covered under a member's medical benefit (Part B benefit). It does not address instances when sebelipase alfa (Kanuma) is covered under a member's pharmacy benefit (Part D benefit).

HOME INFUSION

Sebelipase alfa (Kanuma) may be available under the medical benefit for applicable lines of business through home infusion providers. Member's benefit for home infusion should be verified.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS

Sebelipase alfa (Kanuma) was approved by the FDA on December 8, 2015 for individuals with lysosomal acid lipase deficiency. Supplemental approvals for sebelipase alfa (Kanuma) have since been issued by the FDA.

PEDIATRIC USE

The safety and effectiveness of sebelipase alfa (Kanuma) have been established in pediatric individuals aged one month and older.

Description

Lysosomal acid lipase deficiency is an autosomal recessive lysosomal storage disease characterized by a genetic defect in the lipase A, lysosomal acid type (LIPA) gene resulting in a marked decrease or loss of activity of the lysosomal acid lipase (LAL) enzyme. The clinical expression of the disease is quite variable due to the varying levels of residual enzyme activity in the individuals with the disease. There have been more than 100 LIPA mutations identified which can result in the disease being expressed in different manners and cause the individuals with the disease to respond in different ways to the treatment. LAL breaks down lipid to become free cholesterol and free fatty acid. Free cholesterol and free fatty acids act as transcription factors to down regulate the synthesis and uptake of cholesterol and lipogenesis. Deficient LAL enzyme results in progressive complications due to lysosomal accumulation of cholesteryl esters and triglycerides in multiple organs, including the liver, spleen, intestine, and the walls of the blood vessels.

Infant LAL deficiency, also known as Wolman disease, is rapidly progressive, typically presents within the first weeks of life, and affected infants usually die within six to twelve months. The most common gene disorders in Wolman disease are missense mutations and reading frame alterations which lead to the individuals having little to no LAL activity. The common symptoms for the disease in infants are prominent hepatosplenomegaly, diarrhea and vomiting, malabsorption, growth failure, adrenal gland calcification, and liver failure.

Pediatric and adult LAL deficiency, also known as cholesteryl ester storage disease (CESD), has a mean age of onset of five years. The most common LIPA gene mutation, found in about half of individuals with LAL deficiency that

begins in childhood or later, is called a splice-site mutation where there is a substitution of guanine for adenine near an area of the gene called exon 8 (IVS8-1G>A). The progression can be variable with the primary symptom s of serum lipid abnormalities, hepatosplenomegaly, and/or elevated liver enzymes. Individuals with this form of LAL deficiency usually have a less severe clinical impact from the disease due to some residual enzyme activity. The morbidity/mortality of CESD results from the accumulation of cholesteryl ester and triglycerides in different tissues resulting in atherosclerosis, liver disease/liver failure, complications of hypersplenism, and/or malabsorption.

Sebelipase alfa (Kanuma) was approved by the US Food and Drug Administration (FDA) on December 8, 2015 for the treatment of individuals with a diagnosis of lysosomal acid lipase deficiency. Sebelipase alfa (Kanuma) is a recombinant human lysosomal acid lipase catalyzing the hydrolysis of cholesteryl ester to free cholesterol and free fatty acids. The drug binds to cell surface receptors on the lysosomes and is subsequently internalized into the lysosomes to carry out the enzymatic activity. Prior to the FDA approval of sebelipase alfa (Kanuma), the treatments for LAL deficiency consisted of supportive care/medical management, hematopoietic stem cell transplantation (HSCT), or liver transplantation. These other treatments have had varying degrees of success in treating individuals with LAL deficiency. The literature discusses varying rates of mortality associated with these interventions. None of the interventions treat the underlying disease process, so the individual will often continue to experience ongoing tissue and organ damage.

CLINICAL STUDIES

A multicenter, open-label, single-arm clinical study on the efficacy of sebelipase alfa (Kanuma) was conducted in nine infants with LAL deficiency who had growth failure or other evidence of rapidly progressive disease prior to six months of age. Efficacy was assessed by comparing the survival of infants treated with sebelipase alfa (Kanuma) to 21 historical cohort infants with a similar age at disease presentation and clinical characteristics who were not treated with sebelipase alfa (Kanuma). Of the nine infants on sebelipase alfa (Kanuma), six survived beyond 12 months of age compared to the historical cohort infants with zero surviving past 12 months, all of whom died by eight months of age. The median age of the six infants who survived beyond 12 months was 18.1 months.

The safety and efficacy of sebelipase alfa (Kanuma) were assessed in 66 pediatric and adult individuals with late-onset LAL deficiency, age range four to 58 years, in a multicenter, double-blind, placebo-controlled trial. At the completion of the 20-week double-blind period, the sebelipase alfa (Kanuma)-treated group had a statistically significant improvement in percent change from baseline in low density lipoprotein-cholesterol (LDL-c), non-high density lipoprotein-cholesterol (non-HDL-c), triglycerides, and HDL-c than the placebo group. Individuals treated with sebelipase alfa (Kanuma) had a larger reduction from baseline in alanine aminotransferase (ALT) values and liver fat content compared to individuals treated with placebos.

Successive dose escalations up to 5 mg/kg once weekly due to suboptimal clinical response were assessed in a clinical study (Jones 2017). Nine individuals received a median duration of exposure to 5 mg/kg once weekly of 33 months. Six of these individuals were alive at their last follow up at three years, and two were alive at their last follow up at five years. Of the nine individuals, six experienced normalization of ALT and/or AST which had remained abnormal on the lower dose of sebelipase alfa (Kanuma).

DOSE ESCALATIONS

Given the population and indications, there are limited published peer-reviewed literature sources describing the results of individuals who have the dosage of sebelipase alfa (Kanuma) increased beyond the baseline dosage of 1 mg/kg every other week. Jones et al. (2017) in Survival in infants treated with sebelipase alfa for lysosomal acid lipase deficiency: an open-label, multicenter, dose-escalation study and Vijay et al. (2021) in Long-term survival with sebelipase alfa enzyme replacement therapy in infants with rapidly progressive lysosomal acid lipase deficiency: final results from 2 open-label studies discuss infants in their respective clinical trials who had their dosages increased due to decreased efficacy. Burton (2015) in A phase 3 trial of sebelipase alfa in lysosomal acid lipase deficiency and later in Burton (2022) Sebelipase alfa in children and adults with lysosomal acid lipase deficiency: final results of the ARISE study discusses pediatric and adult individuals who had their dosages increased due to decreased efficacy as well. None of these published studies stratify and specify the individual results into dosage cohorts or discuss if the higher dosage of the drug produced statistically & clinically significant improvements in the individual's clinical picture. They do discuss in the supplemental information for the clinical trials what criteria they used to determine when a dosage should be increased. There are case studies in the published literature that describe individuals who have been treated with increased dosages of sebelipase alfa (Kanuma). The outcomes of the dosage increases varied with some individuals deriving increased efficacy from the increased dosage, and other individuals who did not derive increased efficacy from the increased dosage and required additional treatments to control the effects of the disease. Given the prevalence and severity of disease states, prognoses, and any associated clinical failures and/or progressions among other factors, the aforementioned data serve as the guide to make clinical decisions regarding

dose escalations for Kanuma in specifically evaluated instances per previously researched and expertly devised protocols.

OFF-LABEL INDICATIONS

There may be additional indications contained in the Policy section of this document due to evaluation of criteria highlighted in the Company's off-label policy, and/or review of clinical guidelines issued by leading professional organizations and government entities.

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Coding

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

CPT Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

ICD - 10 Diagnosis Code Number(s)
E75.5 Other lipid storage disorders

HCPCS Level II Code Number(s)
J2840 Injection, sebelipase alfa, 1 mg

Revenue Code Number(s)
N/A

Policy History

Revisions From MA08.078e:

03/28/2025	The policy has been reviewed and reissued to communicate the Company's continuing position on sebelipase alfa (Kanuma®).
05/07/2024	The policy has been reviewed and reissued to communicate the Company's continuing position on sebelipase alfa (Kanuma®).
09/05/2023	The policy has been reviewed and reissued to communicate the Company's continuing position on sebelipase alfa (Kanuma®).
09/26/2022	This version of the policy will become effective 09/26/2022. The following policy criteria have been **revised**: The Dosage and Frequency Requirements, and definitions of suboptimal clinical responses, were revised in accordance with US Food and Drug Administration labeling (11/19/2021) and specific reliable evidence including peer-reviewed literature: Information concerning dosage titration was added for both infants with rapidly progressive lysosomal acid lipase (LAL) deficiency and for pediatric and adult individuals with LAL deficiency

Revisions From MA08.078d:

05/24/2021	The policy has been reviewed and reissued to communicate the Company's continuing position on sebelipase alfa (Kanuma®)
06/22/2020	This version of the policy will become effective 06/22/2020. This policy was updated to clarify the coverage position of sebelipase alfa (Kanuma®) regarding its genetic testing results.

Revisions From MA08.078c:

09/25/2019	This policy has been reissued in accordance with the Company's annual review process.
12/03/2018	This version of the policy will become effective 12/03/2018. This policy was updated to include additional coverage criteria, including diagnostic testing, continuation therapy, and Dosage and Frequency.

Revisions From MA08.078b:

06/06/2018	This policy has been reissued in accordance with the Company's annual review process.
06/07/2017	The policy has been reviewed and reissued to communicate the Company's continuing position on sebelipase alfa (Kanuma).
01/01/2017	This policy has been identified for the HCPCS code update, effective 01/01/2017. The following HCPCS code has been **termed** from this policy: C9478 Injection, sebelipase alfa, 1 mg The following NOC code has been **removed** from this policy and is replaced by the following HCPCS code: **REMOVED:** J3590 Unclassified biologics **REPLACED WITH:** J2840 Injection, sebelipase alfa, 1 mg

Revisions From MA08.078a:

07/01/2016	This policy has been identified for the HCPCS code update, effective 07/01/2016. The following NOC code has been **removed** from this policy and is replaced by the following

	HCPCS code: **REMOVED:** C9399 Unclassified drugs or biologicals **REPLACED WITH:** C9478 Injection, sebelipase alfa, 1 mg

Revisions From MA08.078:

02/24/2016	This new policy has been developed to communicate of the Company's coverage criteria for sebelipase alfa (Kanuma®).

Version Effective Date:
09/26/2022
Version Issued Date:
09/26/2022
Version Reissued Date:
03/28/2025