BlueCross BlueShield of North Carolina

Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders olipudase alfa-rpcp (Xenpozyme)

INTRAVENOUS INFUSION FOR ADMINISTRATION BY A HEALTHCARE PROFESSIONAL

PRIOR REVIEW/CERTIFICATION REQUEST FOR SERVICES FORM

INCOMPLETE FORMS MAY DELAY PROCESSING

ALL NC PROVIDERS MUST PROVIDE THEIR 5-DIGIT Blue Cross NC PROVIDER ID# BELOW

PATIENT NAME	BLUE CROSS NC MEMBER ID NUMBER	PATIENT DATE OF BIRTH

REQUESTING PROVIDER INFORMATION		SERVICING PROVIDER OR FACILITY LOCATION (for services to be performed outside of the physician office)	
Provider Name		**Servicing Provider**	
Provider #, Tax ID # or NPI		**Facility Name**	
Street, Bldg., Suite #		**Servicing provider or Facility #, Tax ID # or NPI**	
City/State/Zip code		**Street, Bldg., Suite #**	
Phone #		**City/State/Zip code**	
Fax #			
PLACE OF SERVICE: ☐ Home ☐ Office ☐ Outpatient hospital ☐ Specialty Pharmacy			
Specialty Pharmacy:		**Specialty Pharmacy NPI:**	
HCPCS CODE:		**CPT/Other billing code:**	
Primary Diagnosis:		**ICD-10:**	

Please answer the following questions for INITIAL coverage and submit medical record documentation:

See pages 3 for continuation coverage; see page 4 for quantity limit exceptions

1. Does the patient have a diagnosis of **acid sphingomyelinase deficiency (ASMD)** type A/B OR type B?.....☐ Yes ☐ No
   Please submit medical record documentation related to medical necessity criteria.
2. Does the patient have documented deficiency of acid sphingomyelinase as measured in peripheral leukocytes, cultured fibroblasts or lymphocytes?.....☐ Yes ☐ No
3. Is the patient less than 18 years of age?.....☐ Yes ☐ No
   a. Does the patient have a spleen volume ≥ 5 multiple of normal (MN) measured by magnetic resonance imaging (MRI)?.....☐ Yes ☐ No
   b. Does the patient have acute or rapidly progressive neurological abnormalities?.....☐ Yes ☐ No
   c. Does the patient have a delay of gross motor skills?.....☐ Yes ☐ No
4. Is the patient ≥ 18 years of age?.....☐ Yes ☐ No
   a. Does the patient have a spleen volume ≥ 6 multiple of normal (MN) measured by magnetic resonance imaging (MRI)?.....☐ Yes ☐ No
   b. Does the patient have a splenomegaly-related score (SRS) of ≥ 5?.....☐ Yes ☐ No
   c. Does the patient have a diffusing capacity of lung for carbon monoxide (DLCO) measurement ≤ 70% of the predicted normal value?.....☐ Yes ☐ No

****continued on page 2; sign page 2 for prior authorization request****

Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders – *continued*
olipudase alfa-rpcp (Xenpozyme)

5. Does the patient have any of the following conditions:
   a. An active, serious, intercurrent illness?..... ☐ Yes ☐ No
   b. Active hepatitis B or hepatitis C infection?..... ☐ Yes ☐ No
   c. Infection with human immunodeficiency virus (HIV)?..... ☐ Yes ☐ No
   d. Cirrhosis determined by clinical evaluation?..... ☐ Yes ☐ No
   e. Clinically significant arrhythmia, moderate or severe pulmonary hypertension or valvular dysfunction, or < 40% left ventricular ejection fraction by echocardiogram?..... ☐ Yes ☐ No
   f. Malignancy diagnosed with the previous 5 years other than non-melanoma skin cancer?..... ☐ Yes ☐ No
6. Does the patient have any central nervous system manifestations of acid sphingomyelinase deficiency (ASMD)?..... ☐ Yes ☐ No
7. Does the patient have a platelet count $\geq$ 60 x 10^3/uL?..... ☐ Yes ☐ No
8. Does the patient have an international normalized ratio (INR) < 1.5?..... ☐ Yes ☐ No
9. Does the patient have an alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level < 250 IU/L?..... ☐ Yes ☐ No
   a. **If NO,** does the patient have a total bilirubin level < 1.5mg/dL?..... ☐ Yes ☐ No
10. Has the patient had a major organ transplant (bone marrow or liver)?..... ☐ Yes ☐ No
11. Is the provider a specialist in the area of the patient's diagnosis (e.g., Geneticist, Hepatologist, Pulmonologist)?..... ☐ Yes ☐ No
12. Will the injection or infusion of the requested medication be administered in an **inpatient or outpatient hospital setting**?..... ☐ Yes ☐ No
    If YES, please answer the Site of Care questions on pages 5-6.
13. Is the requested quantity within the maximum units allowed (see table on page 6)?..... ☐ Yes ☐ No
    If NO, please complete page 4 for a quantity limit exception.

Please certify the following by signing and dating below:
I certify that I have been authorized to request prior review and certification for the above requested service(s). I further certify that my patient's medical records accurately reflect the information provided. I understand that Blue Cross NC may request medical records for this patient at any time in order to verify this information. I further understand that if Blue Cross NC determines this information is not reflected in my patient's medical records, Blue Cross NC may request a refund of any payments made and/or pursue any other remedies available.
Prescriber's Signature (Required):_____ **Date**:_____

For Blue Cross NC members, fax form to 1-888-348-7332

BlueCross BlueShield of North Carolina

Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders - CONTINUATION
olipudase alfa-rpcp (Xenpozyme)

INTRAVENOUS INFUSION FOR ADMINISTRATION BY A HEALTHCARE PROFESSIONAL

PRIOR REVIEW/CERTIFICATION REQUEST FOR SERVICES FORM

INCOMPLETE FORMS MAY DELAY PROCESSING

ALL NC PROVIDERS MUST PROVIDE THEIR 5-DIGIT Blue Cross NC PROVIDER ID# BELOW

PATIENT NAME	BLUE CROSS NC MEMBER ID NUMBER	PATIENT DATE OF BIRTH

REQUESTING PROVIDER INFORMATION		SERVICING PROVIDER OR FACILITY LOCATION (for services to be performed outside of the physician office)	
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Street, Bldg., Suite #		**Servicing provider or Facility #, Tax ID # or NPI**	
City/State/Zip code		**Street, Bldg., Suite #**	
Phone #		**City/State/Zip code**	
Fax #			

PLACE OF SERVICE: ☐ Home ☐ Office ☐ Outpatient hospital ☐ Specialty Pharmacy

Specialty Pharmacy:	**Specialty Pharmacy NPI:**
HCPCS CODE:	**CPT/Other billing code:**
Primary Diagnosis:	**ICD-10:**

Please answer the following questions for CONTINUATION coverage, and submit medical record documentation:

1. Was the patient approved for initial coverage for the requested medication through Blue Cross NC?.....☐ Yes ☐ No
   If NO, please answer all questions on pages 1-2. If YES, please answer the following questions AND submit medical record documentation related to medical necessity criteria.
2. Has the patient demonstrated clinical benefit since initiating therapy?.....☐ Yes ☐ No
   Please submit medical record documentation.
3. Has the patient experienced disease stabilization since initiating therapy?.....☐ Yes ☐ No
   Please submit medical record documentation.
4. Will the injection or infusion of the requested medication be administered in an **inpatient or outpatient hospital setting**?.....☐ Yes ☐ No
   If YES, please answer the Site of Care questions on pages 5-6.
5. Is the requested quantity within the maximum units allowed (see table on page 6)?.....☐ Yes ☐ No
   If NO, please complete page 4 for a quantity limit exception.

Please certify the following by signing and dating below:
I certify that I have been authorized to request prior review and certification for the above requested service(s). I further certify that my patient's medical records accurately reflect the information provided. I understand that Blue Cross NC may request medical records for this patient at any time in order to verify this information. I further understand that if Blue Cross NC determines this information is not reflected in my patient's medical records, Blue Cross NC may request a refund of any payments made and/or pursue any other remedies available.

Prescriber's Signature (Required):_____ **Date**:_____

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BlueCross BlueShield of North Carolina

Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders olipudase alfa-rpcp (Xenpozyme) - QUANTITY LIMIT EXCEPTION

INTRAVENOUS INFUSION FOR ADMINISTRATION BY A HEALTHCARE PROFESSIONAL

PATIENT NAME	BLUE CROSS NC MEMBER ID NUMBER	PATIENT DATE OF BIRTH

REQUESTING PROVIDER INFORMATION		SERVICING PROVIDER OR FACILITY LOCATION (for services to be performed outside of the physician office)	
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City/State/Zip code		**Street, Bldg., Suite #**	
Phone #		**City/State/Zip code**	
Fax #			
PLACE OF SERVICE: ☐ Home ☐ Office ☐ Outpatient hospital ☐ Specialty Pharmacy			
Specialty Pharmacy:		**Specialty Pharmacy NPI:**	
HCPCS CODE:		**CPT/Other billing code:**	
Primary Diagnosis:		**ICD-10:**	

FOR COVERAGE OVER THE FDA LABELED DOSING (SEE TABLE ON PAGE 6), PLEASE SELECT THE REQUESTED MEDICATION AND ANSWER THE FOLLOWING QUESTIONS:

Please note: This medication requires a prior authorization before a quantity limit override can be considered. Before submitting a request for a quantity level override, please ensure that a prior approval authorization has been submitted and/or approved (pages 1-2 or page 3). Otherwise, this request will deny.

Requested units: _____

Please enter quantity as a numeric value with one decimal place (ex. 1.0, 1.5)*

Please provide the patient's current weight: _____ ☐ kg ☐ lbs

In the space provided, please document support for the requested Quantity Limit Exception (this may include documented clinical rationale and/or medical records).

_____

_____

_____

Please certify the following by signing and dating below:

I certify that I have been authorized to request prior review and certification for the above requested service(s). I further certify that my patient's medical records accurately reflect the information provided. I understand that Blue Cross NC may request medical records for this patient at any time in order to verify this information. I further understand that if Blue Cross NC determines this information is not reflected in my patient's medical records, Blue Cross NC may request a refund of any payments made and/or pursue any other remedies available.

Prescriber's Signature (Required):_____ **Date**:_____

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BlueCross BlueShield of North Carolina

Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders – SITE OF CARE
olipudase alfa-rpcp (Xenpozyme)
INTRAVENOUS INFUSION FOR ADMINISTRATION BY A HEALTHCARE PROFESSIONAL

PATIENT NAME	BLUE CROSS NC MEMBER ID NUMBER	PATIENT DATE OF BIRTH

REQUESTING PROVIDER INFORMATION		SERVICING PROVIDER OR FACILITY LOCATION (for services to be performed outside of the physician office)	
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Specialty Pharmacy:		**Specialty Pharmacy NPI:**	
HCPCS CODE:		**CPT/Other billing code:**	
Primary Diagnosis:		**ICD-10:**	

PLEASE SELECT THE REQUESTED MEDICATION AND ANSWER THE FOLLOWING QUESTIONS:

Please note: *This medication requires a* ***prior authorization*** *before Site of Care can be considered. Before submitting a request for Site of Care, please ensure that a prior approval authorization has been submitted and/or approved (pages 1-2 or page 3). Otherwise, this request will deny.*

1. Is the injection/infusion being administered in an **inpatient setting**?.....☐ Yes ☐ No
   If YES, please answer the following questions:
   a. Is the sole purpose of the inpatient admission for giving the injection/infusion?.....☐ Yes ☐ No
   b. Is this an **emergent** admission/request (the patient presented to the hospital via emergency room or transferred inpatient from another facility)?.....☐ Yes ☐ No
2. Is the injection/infusion being administered in an **outpatient hospital setting**?.....☐ Yes ☐ No
   If YES, please answer the following questions:
   a. Does the patient have a history of mild adverse events that have not been successfully managed through mild pre-medication (e.g., diphenhydramine, acetaminophen, steroids, fluids, etc.)?.....☐ Yes ☐ No
   b. Is the patient unable to physically and cognitively adhere to the treatment schedule and regimen complexity?.....☐ Yes ☐ No
   c. Is the patient new to therapy (defined as initial injection/infusion OR less than 3 months since the initial injection/infusion)?.....☐ Yes ☐ No
   d. Is this the first injection/infusion after 6 months of no injections/infusions for medications with approved dosing intervals of less than 6 months?.....☐ Yes ☐ No
   e. Is this the first injection/infusion after at least a 1-month gap in therapy outside of the approved dosing interval for medications requiring every 6 months dosing duration?.....☐ Yes ☐ No
   f. Is this request required due to a change in formulation of the requested medication?.....☐ Yes ☐ No

****NOTE: continued on page 6, please sign page 6 for Site of Care request****

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Enzyme Replacement Therapy (ERT) for Lysosomal Storage Disorders – SITE OF CARE
olipudase alfa-rpcp (Xenpozyme)
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Prescriber's Signature (Required):_____ **Date**:_____

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FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
Olipudase alfa-rpcp (Xenpozyme®) intravenous (IV) infusion	Acid sphingomyelinase deficiency (ASMD)	Patients ≥ 18 years old: IV infusion every 2 weeks Week 0: 0.1 mg/kg Weeks 2-4: 0.3 mg/kg Weeks 6-8: 0.6 mg/kg Week 10: 1 mg/kg Week 12: 2 mg/kg Week 14: 3 mg/kg (Recommended maintenance dose) Patients < 18 years old: IV infusion every 2 weeks Week 0: 0.03 mg/kg Weeks 2: 0.1 mg/kg Weeks 4-6: 0.3mg/kg Weeks 8-10: 0.6 mg/kg Week 12: 1 mg/kg Week 14: 2 mg/kg Week 16: 3 mg/kg (Recommended maintenance dose)	C9399** J3490** J3590**	Patients ≥ 18 years old: 5,841 units Patients < 18 years old: 5,574 units

***Maximum units allowed for duration of approval**
****Non-specific assigned HCPCS codes, must submit requested product NDC**