Clinical Criteria Worksheet:
Luxturna™ (voretigene neparvovec-rzyl)

Claim Submission

- Claim processing may be delayed if the information submitted in this worksheet is illegible.
- If the worksheet is left blank or information is missing the claim will be rejected for not enough documentation and reimbursement will be delayed.
- A claim should not be submitted until the drug has been administered to the patient.
- The manufacturer invoice showing the acquisition cost of the drug administered, including all discounts, rebates, and incentives must be submitted with the claim. The invoice must be dated within 6 months prior to the date of service and/or should include the expiration date of the drug, or it will be rejected for not enough documentation.

Enrollee Information

Enrollee Last Name:

Enrollee First Name:

Date of Birth (MM/DD/YYYY): ___ / ___ / ___

Enrollee Medicaid ID (2 letters, 5 numbers, 1 letter):

Address:

City, Town or Post Office:

State:

ZIP Code:

Prescriber Information

Prescriber Last Name:

Prescriber First Name:

National Provider Identifier (NPI) Number:

Preferred Contact (Telephone Number)

___ – ___ – ___

Enrollee Last Name: | **Enrollee First Name:**

Clinical Criteria – Drug Information

Drug Administration:

Provide the date of drug administration (MM/DD/YYYY):

__ __ / __ __ / __ __ __ __

Provide the expiration date of the drug if the invoice date is greater than 6 months from the date of drug administration (MM/DD/YYYY):

__ __ / __ __ / __ __ __ __

Drug Name and Strength:

☐ LUXTURNA VIAL

Directions: ____

Quantity: ____

Clinical Criteria – Diagnosis

1. ☐ Retinal dystrophy with confirmed bi-allelic RPE65 mutation

2. Luxturna™ will be approved for one treatment per eye per patient for their lifetime and must be done separately in each eye, with at least six days between surgical procedures. Has the patient received any prior doses of Luxturna™?

   ☐ Yes ☐ No

   Prior doses: ____

If this is the completion of therapy (i.e. treatment in the 2nd eye) and you have already received payment for the previous administration of this medication, provide attestation signature on page 3. Additional information on page 3 is not necessary.

Enrollee Last Name: | | | | | | | | | | | | |

Enrollee First Name: | | | | | | | | | | | | |

3. Does the patient have documented genetic testing confirming the presence of mutations in both copies of the RPE65 gene?

   ☐ Yes ☐ No

   If **Yes**, please provide the date of the lab test result:

   ☐☐ / ☐☐ / ☐☐☐☐

4. Does the patient have viable retinal cells as determined by the treating physician(s)?

   ☐ Yes ☐ No

5. Is the patient 12 months of age or older?

   ☐ Yes ☐ No

Attestation

I attest that this is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by the New York State Medicaid Program.

______________________________ ______________

Prescriber Signature (Required) **Date (MM/DD/YYYY)**