LUXTURNATA™ (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Patients must have viable retinal cells as determined by the treating physicians.¹

Spark Therapeutics is committed to working with you and providing detailed information to assist in reimbursement for LUXTURNATA and related support services.

This guide was created to provide information to Treatment Centers to help with the reimbursement process for LUXTURNATA.

Please see here for Important Safety Information for LUXTURNATA. Please see here for the full US Prescribing Information for LUXTURNATA.

Indication
LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.
Patients must have viable retinal cells as determined by the treating physicians.

Important Safety Information

Warnings and Precautions
• **Endophthalmitis** may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.
• **Permanent decline in visual acuity** may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.
• **Retinal abnormalities** may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.
• **Increased intraocular pressure** may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.
• **Expansion of intraocular air bubbles** Instruct patients to avoid air travel, travel to high elevations or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.
• **Cataract** Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

Adverse Reactions
• In clinical studies, ocular adverse reactions occurred in 66% of study participants (57% of injected eyes), and may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.
• The most common adverse reactions (incidence ≥ 5% of study participants) were conjunctival hyperemia (22%), cataract (20%), increased intraocular pressure (15%), retinal tear (10%), dellen (thinning of the corneal stroma) (7%), macular hole (7%), subretinal deposits (7%), eye inflammation (5%), eye irritation (5%), eye pain (5%), and maculopathy (wrinkling on the surface of the macula) (5%).

Immunogenicity
Immune reactions and extra-ocular exposure to LUXTURNA in clinical studies were mild. No clinically significant cytotoxic T-cell response to either AAV2 or RPE65 has been observed. In clinical studies, the interval between the subretinal injections into the two eyes ranged from 7 to 14 days and 1.7 to 4.6 years. Study participants received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye, which may have decreased the potential immune reaction to either AAV2 or RPE65.

Pediatric Use
Treatment with LUXTURNA is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during the cell proliferation. The safety and efficacy of LUXTURNA have been established in pediatric patients. There were no significant differences in safety between the different age subgroups.

Please see here for the full US Prescribing Information for LUXTURNA.
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Introducing the Spark Therapeutics Generation Patient ServicesSM support team

Benefits investigation, prior authorization, and appeals

Financial assistance options

Ordering and distribution

Coding and claims

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Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
OVERVIEW OF THE PATIENT JOURNEY WITH LUXTURNA™
(VORETIGENE NEPARVOVEC-RZYL)

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
LUXTURNA is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physicians. While each patient who receives LUXTURNA experiences his or her own distinct treatment journey, the outline below can help when working with your enrolled patients and their caregivers.

**Genetically confirmed diagnosis**
- Referring physician
- Patient

**Spark Therapeutics Generation Patient Services**
- Referring physician
- Patient/caregiver
- Spark Tx

**Treatment decision**
- Patient/caregiver
- Treatment center physician(s)

**Access**
- Patient/caregiver
- Spark Tx GPS
- Treatment Center physician(s)

**Scheduling and logistics**
- Patient/caregiver
- Spark Tx GPS
- Payer
- Treatment Center physician(s)
- Specialty Pharmacy

**Surgery**
- Patient/caregiver
- Spark Tx GPS
- Treatment Center physician(s)

**Follow-up**
- Referring physician
- Treatment Center physician(s)
- Spark Tx GPS

**GPS=Generation Patient Services; Spark Tx=Spark Therapeutics.**

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**Work with Spark Therapeutics Generation Patient Services to help coordinate coverage and care for your enrolled patients.**

**Important Safety Information**

**Warnings and Precautions**
- **Endophthalmitis** may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.
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**Outline of the patient journey with LUXTURNA™ (voretigene neparvovec-rzyl)**

LUXTURNA is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physicians. While each patient who receives LUXTURNA experiences his or her own distinct treatment journey, the outline below can help when working with your enrolled patients and their caregivers.

**Genetically confirmed diagnosis**
- Referring physician
- Patient/ caregiver
  - Referring physician confirms biallelic RPE65 mutation-associated retinal dystrophy diagnosis via genetic testing

**Access**
- Patient/ caregiver
- Spark Tx
- GPS

**Scheduling and logistics**
- Patient/ caregiver
- Treatment Center physician(s)
- Payer

**Surgery**
- Patient/ caregiver
- Spark Tx
- GPS

**Follow-up**
- Referring physician
- Treatment Center physician(s)
- Spark Tx

**Treatment decision**
- Patient/ caregiver
- Treatment center physician(s)

**Important Safety Information**

**Warnings and Precautions**
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Outline of the patient journey with LUXTURNATM (voretigene neparvovec-rzyl)

LUXTURNA is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physicians.1

While each patient who receives LUXTURNA experiences his or her own distinct treatment journey, the outline below can help when working with your enrolled patients and their caregivers.

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Important Safety Information

Warnings and Precautions

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- Spark Tx GPS
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**Follow-up**
- Referring physician
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**IMPORTANT SAFETY INFORMATION**

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Please see [here](#) for Important Safety Information for LUXTURNA.

Please see [here](#) for the full US Prescribing Information for LUXTURNA.

INTRODUCING SPARK THERAPEUTICS GENERATION PATIENT SERVICES℠

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
Spark Therapeutics Generation Patient Services℠ offers dedicated support that's customized for your patients.

Spark Therapeutics Generation Patient Services can help you and your enrolled patients and their caregivers understand the coverage process, work with insurance companies, access financial assistance, and receive resources and support as needed.

Spark Therapeutics Generation Patient Services overview

Spark Therapeutics Generation Patient Services can support your enrolled patients by:

- Providing a caring support team for patients/caregivers from confirmed diagnosis through post-surgery follow-up
- Ensuring a single point of contact to help navigate insurance coverage, and connecting your patients with financial assistance resources as needed
- Helping to coordinate the logistics of your patients’ Treatment Center visits
- Answering any nonmedical questions your patients may have along the way
- Assisting patients with travel logistics and planning, and connecting them and their caregivers to resources that can provide support during the treatment process
  - Because of legal requirements, some services and resources are not available to patients with government insurance

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
Enrolling in Spark Therapeutics Generation Patient Services℠

To enroll patients in Spark Therapeutics Generation Patient Services,* the referring healthcare provider must help them or their caregiver complete an enrollment form. While the program is optional, we encourage patients to take advantage of this free service.

Once patients are enrolled, Spark Therapeutics Generation Patient Services will help schedule a consultation at their designated Treatment Center. In each case, the Treatment Center will be identified based on the patient’s insurance and home location.

If a patient is already at their designated Ocular Gene Therapy Treatment Center, an enrollment form is not necessary. However, a statement of medical necessity (SMN) is still needed to receive Spark-sponsored support throughout the access process.

To contact Spark Therapeutics Generation Patient Services, you can:

**Call toll-free:**
1-833-SPARK-PS (1-833-772-7577)
8:30 AM to 6:30 PM ET,
Monday through Friday

**Email**
mysparkgeneration@sparktx.com

**Fax**
678-727-1501

*Participation in Spark Therapeutics Generation Patient Support Services is voluntary. Patients may choose to participate in all, some, or none of the services offered. Participating or deciding not to participate in these services will have no effect on your patients’ ability to get treatment or the nature of your patients’ treatment or care. Generation Patient Services does not provide medical advice.

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
BENEFITS INVESTIGATION, PRIOR AUTHORIZATION, AND APPEALS

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
Getting started with access

Each patient journey with LUXTURNATM (voretigene neparvovec-rzyl) is unique—and Spark Therapeutics Generation Patient ServicesSM is here to help

Spark Therapeutics Generation Patient Services* can assist with benefits investigations, prior authorizations, and appeals processes, and can work with insurers to obtain optimal coverage for the particular health plan(s) of each enrolled patient.

To receive support throughout the access process, work with your patient and/or their caregiver to complete an SMN

- The SMN starts the benefits investigation process, including determining coverage status
- The SMN must be completed by a surgeon or prescribing physician at your Treatment Center
- Once an SMN has been received along with Patient Authorization to Use and Disclose Health Information, your patient’s Spark Therapeutics Generation Patient Services team will communicate the next steps
- On the first day of the month of scheduled treatment administration, Spark Therapeutics Generation Patient Services can confirm that there have been no changes and that coverage is in place

You do not need to complete an SMN if your facility does not want assistance from Spark Therapeutics Generation Patient Services during the benefits investigation process for LUXTURNA.

Please refer to the appendix or visit the Spark Therapeutics Generation Patient Services website at https://mysparkgeneration.com/pdf/SMN_Form_iPDF.pdf to download the SMN.

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Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
Prior authorization and required documentation

• Prior authorization may be required for treatment with LUXTURNATM (voretigene neparvovec-rzyl)
• Each payer may have different requirements regarding the prior authorization process
• Expand below to see examples of authorization documentation and coverage parameters

Spark Therapeutics Generation Patient ServicesSM is available to assist with the prior authorization process.

Important Safety Information
Warnings and Precautions (cont’d)
• Retinal abnormalities may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.

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Prior authorization and required documentation

- Prior authorization may be required for treatment with LUXTURNATM (voretigene neparvovec-rzyl)
- Each payer may have different requirements regarding the prior authorization process
- Expand below to see examples of authorization documentation and coverage parameters

<table>
<thead>
<tr>
<th>Identify specific documents that may need to be submitted with the request, such as:</th>
<th>Determine potential prior authorization coverage parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statement of medical necessity</td>
<td>Prescription and insurance information</td>
</tr>
<tr>
<td>Chart notes</td>
<td>Diagnosis limitations</td>
</tr>
<tr>
<td>Precertification or precertification number</td>
<td>Coverage status</td>
</tr>
<tr>
<td>Specific payer prior authorization form</td>
<td>Submission requirements</td>
</tr>
</tbody>
</table>

LUXTURNA US Prescribing Information

- Relevant literature, including previously published standards of care

Clinical documents related to the disease, including:
- Diagnostic evidence of inherited retinal disease, such as genetic testing
- Clinical presentation and duration of the symptoms
- Current supportive care management
- Care plan
- Other relevant aspects of patient history

- Note: additional forms may be needed in case of specific requests based on payer needs

Spark Therapeutics Generation Patient ServicesSM is available to assist with the prior authorization process.

**Important Safety Information**

**Warnings and Precautions (cont’d)**

- **Retinal abnormalities** may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
Coverage parameters: surgery and observation

Info

- The subretinal administration of LUXTURNA™ (voretigene neparvovec-rzyl) to each eye should be performed on separate days within a close interval, but no fewer than 6 days apart.
- Initiate supine head positioning immediately in the post-operative period. Upon discharge, advise patients to rest in a supine position as much as possible for 24 hours.
- After the treatment procedure, patients should be instructed to avoid air travel, travel to high elevations, or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye.
  - It may take one week or more following injection for the air bubble to dissipate.
  - A change in altitude while the air bubble is still present can result in irreversible vision loss.
  - The dissipation of the air bubble must be verified through ophthalmic examination.

Action

- It’s important to establish the parameters that the patients’ payers may cover for length of stay in the hospital during administration of LUXTURNA and follow up.
- Insurance verification may be required if follow up is requested by the IRD specialist or surgeon beyond the typical post-operation appointment.

Important Safety Information

Warnings and Precautions (cont’d)

- **Increased intraocular pressure** may occur after subretinal injection of LUXTURNA. Monitor and manage intraocular pressure appropriately.

- **Expansion of intraocular air bubbles** Instruct patients to avoid air travel, travel to high elevations or scuba diving until the air bubble formed following administration of LUXTURNA has completely dissipated from the eye. It may take one week or more following injection for the air bubble to dissipate. A change in altitude while the air bubble is still present can result in irreversible vision loss. Verify the dissipation of the air bubble through ophthalmic examination.

- **Cataract** Subretinal injection of LUXTURNA, especially vitrectomy surgery, is associated with an increased incidence of cataract development and/or progression.

Please see here for additional Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.

Potential provider network restrictions

Info

- Patients who receive LUXTURNA™ (voretigene neparvovec-rzyl) may face restrictions from their insurers because the surgeon and/or Treatment Center is out of network or out of state
- Each payer may have a network of participating providers who have agreed to provide care under specific terms
  - For example, for patients with private commercial insurance, payers may not cover services provided by nonpreferred providers or may associate those services with higher out-of-pocket costs
  - For Medicaid beneficiaries, coverage may be limited to participating in-state providers
  - Patients enrolled in Medicaid Managed Care may also only be able to receive care from in-network providers within their state
- Payers may grant coverage exceptions if medical necessity is established

Action

- For a patient to receive a waiver on grounds of medical necessity, your facility may want to:
  - Verify the state and/or network participation status of the physician(s) and/or your treatment facility
  - Determine and record the patient out-of-pocket costs for out-of-state/out-of-network providers
  - Find out if there is an exception process for patients seeking care out of state and/or out of network, and if this depends on whether the patient is covered through commercial or government insurance

Spark Therapeutics Generation Patient Services℠ can help your facility determine potential network restrictions and navigate this process.

Important Safety Information

Adverse Reactions
- In clinical studies, ocular adverse reactions occurred in 66% of study participants (57% of injected eyes), and may have been related to LUXTURNA, the subretinal injection procedure, the concomitant use of corticosteroids, or a combination of these procedures and products.

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
Coordination of benefits for multiple payers

**Info**

- Your patients eligible for LUXTURNA™ (voretigene neparvovec-rzyl) may have multiple payers that provide benefit coverage (for example, a commercial health plan and Medicaid/Medicare)

**Action**

- During the benefits investigation process, your facility may want to establish which payer is primary, and which are secondary and tertiary (if applicable)
- After establishing the order of benefits, consider following the instructions from each payer on coordination of benefits for reimbursement/payment
- Although coverage may not be typically provided through a pharmacy benefits manager, this may be the case in certain circumstances. Spark Therapeutics Generation Patient Services℠ can help you coordinate each patient’s coverage needs

Because the prior authorization process may not yet be defined for gene therapy, Spark Generation Patient Services is available to work with you and your patients to determine next steps in the absence of process or policy.

**Important Safety Information**

**Adverse Reactions (cont’d)**

- The most common adverse reactions (incidence ≥ 5% of study participants) were conjunctival hyperemia (22%), cataract (20%), increased intraocular pressure (15%), retinal tear (10%), dellen (thinning of the corneal stroma) (7%), macular hole (7%), subretinal deposits (7%), eye inflammation (5%), eye irritation (5%), eye pain (5%), and maculopathy (wrinkling on the surface of the macula) (5%).

**Immunogenicity**

Immune reactions and extra-ocular exposure to LUXTURNA in clinical studies were mild. No clinically significant cytotoxic T-cell response to either AAV2 or RPE65 has been observed. In clinical studies, the interval between the subretinal injections into the two eyes ranged from 7 to 14 days and 1.7 to 4.6 years. Study participants received systemic corticosteroids before and after subretinal injection of LUXTURNA to each eye, which may have decreased the potential immune reaction to either AAV2 or RPE65.

Please see [here](#) for Important Safety Information for LUXTURNA.
Please see [here](#) for the full US Prescribing Information for LUXTURNA.
Appealing a denial

If your patient’s claim is denied, contact Spark Therapeutics Generation Patient Services™ for assistance with the logistics of the appeals process.

If your prior authorization request for LUXTURNA™ (voretigene neparvovec-rzyl) is denied, you may be able to appeal. Appeals may adhere to each payer’s requirements and include additional information that emphasize the medical necessity of LUXTURNA for the patient. Spark Therapeutics Generation Patient Services is available to walk your facility through the appeals process.

Suggested guidelines for how to appeal:

1. Understand the reason for the denial
2. Determine the reason for the denial (eg, clerical, clinical, or benefit driven)
   - If the denial was for clerical reasons, consider immediately resubmitting the request with the proper information
     • Reasons clerical reasons claims may be denied:
       – Incorrect codes
       – Missing information
       – Incorrect product information
   - If the denial was for clinical reasons, consider evaluating what additional information may be required to demonstrate medical necessity
   - If the denial was for benefits reasons, consider calling the payer to determine if an exception to the benefit may be allowed and to determine the process for such an exception (for example, if LUXTURNA is not yet covered under the insurer’s coverage benefit, or if the patient has no out-of-network benefits and Treatment Center is out of network)
3. Verify the appeals process for the payer
4. Record the correspondence with the payer at every point of the appeals process, including date, time, point of contact, and nature of discussion
5. If your appeal is denied again, work with Spark Therapeutics Generation Patient Services representatives to consider an external review.

Important Safety Information

Pediatric Use
Treatment with LUXTURNA is not recommended for patients younger than 12 months of age, because the retinal cells are still undergoing cell proliferation, and LUXTURNA would potentially be diluted or lost during the cell proliferation. The safety and efficacy of LUXTURNA have been established in pediatric patients. There were no significant differences in safety between the different age subgroups.

Please see here for Important Safety Information for LUXTURNA.
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FINANCIAL ASSISTANCE OPTIONS FOR LUXTURNA™
(VORETIGENE NEPARVOVEC-RZYL)

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
Financial assistance options for LUXTURNA™ (voretigene neparvovec-rzyl)

Your patients eligible for LUXTURNA have options for financial support based on their insurance type

• Commercial insurance
  – If your patients have commercial insurance without secondary/tertiary government insurance, Spark Therapeutics Generation Patient Services™ offers a co-pay assistance program that may help with out-of-pocket costs

• Government insurance
  – If your patients have government insurance, Spark Therapeutics Generation Patient Services can refer them to independent nonprofit 501(c)(3) organizations that may be able to help with out-of-pocket costs
    • The Assistance Fund
    • Patient Access Network Foundation

• Uninsured
  – If your patient is uninsured and has enrolled in Spark Therapeutics Generation Patient Services, Generation Patient Services can help them explore available insurance options

Spark Therapeutics Generation Patient Services can help connect enrolled patients to resources that may assist with out-of-pocket costs.

Please see here for Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.
ORDERING LUXTURNATM
(VORETIGENE NEPARVODEVCE-RZYL)

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
Ordering and distribution processes for LUXTURNATM (voretigene neparvovec-rzyl) may vary from patient to patient

Ordering

• Every patient situation is different. Contact Spark Therapeutics Generation Patient ServicesSM for more information on the ordering process for LUXTURNATM

Distribution

• Spark Therapeutics offers innovative distribution choices for LUXTURNATM
  – We are committed to working with your Treatment Center, patients/caregivers, payers, and other key stakeholders to determine the best fit for you and your patients’ needs
  • Contact Spark Therapeutics Generation Patient Services to learn more

Spark Therapeutics Generation Patient Services is available to provide more information or facilitate the ordering and distribution processes.

Please see here for Important Safety Information for LUXTURNATM.
Please see here for the full US Prescribing Information for LUXTURNATM.
SUBMITTING CLAIMS FOR LUXTURNA™ (VORETIGENE NEPARVOVEC-RZYL)

Please see [here](#) for Important Safety Information for LUXTURNA.
Please see [here](#) for the full US Prescribing Information for LUXTURNA.
Payer billing guidelines can facilitate claims processing and prompt payment

Once your patient has been administered LUXTURNATM (voretigene neparvovec-rzyl), your facility will have to submit a claim to the patient’s insurance plan. Items included in your claim may depend on the site of care and billing entry.

This information is provided for informational purposes only and is not legal advice or official guidance from Spark; it is not intended to maximize or minimize reimbursement. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the Treatment Center, healthcare provider, and patient. Spark makes no guarantee regarding reimbursement for any service or item or that the use of this information will result in coverage or payment for LUXTURNA. Spark is not responsible for any actions providers or payers take in billing or processing LUXTURNA claims.

ICD-10-CM diagnosis coding

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes describe the patient’s medical condition.1 Proper coding of diagnoses is essential and must be based on the information documented in the patient’s medical record, without consideration of the adequacy of the reimbursement levels assigned by payers to specific codes. Coding conventions typically dictate that a patient’s diagnosis (and treatment) be coded to the highest level of specificity possible. Below are ICD-10-CM diagnosis codes that may be applicable for patients to whom LUXTURNA is administered.

Per the US Prescribing Information, LUXTURNA is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physicians.2

<table>
<thead>
<tr>
<th>ICD-10-CM diagnosis code1</th>
<th>Code descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>H35.50</td>
<td>Unspecified hereditary retinal dystrophy</td>
</tr>
<tr>
<td></td>
<td><em>Other indexing guidance for H35.50: Leber’s congenital amaurosis</em></td>
</tr>
<tr>
<td></td>
<td><em>Best’s disease</em></td>
</tr>
<tr>
<td>H35.52</td>
<td>Pigmentary retinal dystrophy</td>
</tr>
<tr>
<td></td>
<td><em>Retinitis pigmentosa</em></td>
</tr>
<tr>
<td>H35.54</td>
<td>Dystrophies primarily involving the retinal pigment epithelium</td>
</tr>
</tbody>
</table>

Indication

LUXTURNA (voretigene neparvovec-rzyl) is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.

Patients must have viable retinal cells as determined by the treating physicians.

Please see [here](#) for Important Safety Information for LUXTURNA. Please see [here](#) for the full US Prescribing Information for LUXTURNA.

Payer billing guidelines can facilitate claims processing and prompt payment (cont’d)

Level I HCPCS codes – CPT
The following CPT codes (either, but not both for one administration of LUXTURNA™ [voretigene neaparvovec-rzyl]) are possible codes to report administration of LUXTURNA. Note that billing both the vitrectomy code and the unlisted procedure code on a single claim for one administration of LUXTURNA could be viewed by some payers as unbundling the subretinal injection from the overall procedure.

<table>
<thead>
<tr>
<th>HCPCS Level I CPT code¹</th>
<th>Code descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT 67036</td>
<td>Vitrectomy, mechanical, pars plana approach</td>
</tr>
<tr>
<td>CPT 67299</td>
<td>Unlisted procedure, posterior segment</td>
</tr>
</tbody>
</table>

Modifiers should be included on the same line as the CPT code to identify the eye to which administration of LUXTURNA occurred.

<table>
<thead>
<tr>
<th>Modifier¹</th>
<th>Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>-RT</td>
<td>Right</td>
</tr>
<tr>
<td>-LT</td>
<td>Left</td>
</tr>
</tbody>
</table>


Important Safety Information (cont’d)

Warnings and Precautions
• **Endophthalmitis** may occur following any intraocular surgical procedure or injection. Use proper aseptic injection technique when administering LUXTURNA, and monitor for and advise patients to report any signs or symptoms of infection or inflammation to permit early treatment of any infection.

• **Permanent decline in visual acuity** may occur following subretinal injection of LUXTURNA. Monitor patients for visual disturbances.

Please see [here](#) for additional Important Safety Information for LUXTURNA. Please see [here](#) for the full US Prescribing Information for LUXTURNA.

Payer billing guidelines can facilitate claims processing and prompt payment (cont’d)

Level II HCPCS codes

A specific Level II HCPCS code is not yet available to describe LUXTURNA™ (voretigene
neparvovec-rzyl). Miscellaneous HCPCS codes should generally be used until a unique code is
assigned.¹ Payer rules and requirements vary regarding the miscellaneous code that should be
used, as well as the supplemental information that must be provided on the claim (eg, product
name, quantity administered, and national drug code [NDC]). Furthermore, when miscellaneous
codes are reported, payers may require submission of additional information such as physicians’
progress notes and invoices. Medicare usually requires the use of a miscellaneous C code (C9399)
instead of a miscellaneous J code in the hospital outpatient or ambulatory surgery center settings.²

C code

<table>
<thead>
<tr>
<th>HCPCS Level II code²</th>
<th>Code descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
</tr>
</tbody>
</table>

(Used in Medicare Outpatient Prospective Payment System [OPPS] for new
drugs and biologicals that are approved by the FDA on or after January 1,
2004, for which a specific HCPCS code has not been assigned.*)

*Centers for Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Ch. 17, §90.2 (April 2014).

J code

<table>
<thead>
<tr>
<th>HCPCS Level II code²</th>
<th>Code descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
</tr>
</tbody>
</table>

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.

Payer billing guidelines can facilitate claims processing and prompt payment (cont’d)

**National Drug Code (NDC)**

Medications approved by the FDA are assigned a 3-segment number known as the National Drug Code (NDC). Some payers, including Medicaid, require that products such as LUXTURNA™ (voretigene neparvovec-rzyl) be billed with the product’s NDC in addition to the HCPCS Level II code described on the previous page. Such payers may require a 10-digit or 11-digit NDC; exact requirements should be confirmed prior to submitting claims.¹ LUXTURNA has been assigned the following NDCs:

<table>
<thead>
<tr>
<th>NDC²</th>
<th>Code descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-digit for package (carton and pouch)</td>
<td>71394-415-01</td>
</tr>
<tr>
<td>11-digit for package (carton and pouch)</td>
<td>71394-0415-01</td>
</tr>
</tbody>
</table>

Please see [here](#) for Important Safety Information for LUXTURNA. Please see [here](#) for the full US Prescribing Information for LUXTURNA.

APPENDIX

Please see here for Important Safety Information for LUXTURNA.
Please see here for the full US Prescribing Information for LUXTURNA.
Appendix

Statement of medical necessity

Spark Therapeutics Generation Patient Services℠ enrollment form

Important Safety Information (cont’d)

Warnings and Precautions

• Retinal abnormalities may occur during or following the subretinal injection of LUXTURNA, including macular holes, foveal thinning, loss of foveal function, foveal dehiscence, and retinal hemorrhage. Monitor and manage these retinal abnormalities appropriately. Do not administer LUXTURNA in the immediate vicinity of the fovea. Retinal abnormalities may occur during or following vitrectomy, including retinal tears, epiretinal membrane, or retinal detachment. Monitor patients during and following the injection to permit early treatment of these retinal abnormalities. Advise patients to report any signs or symptoms of retinal tears and/or detachment without delay.

Please see here for additional Important Safety Information for LUXTURNA. Please see here for the full US Prescribing Information for LUXTURNA.