

## Blue Distinction® Centers for Gene Therapy Ocular Disorders Selection Criteria

### Blue Distinction®

Blue Distinction is a national designation awarded by Blue Cross Blue Shield (BCBS) Plans to recognize providers that demonstrate expertise in delivering quality specialty care – safely, effectively, and cost-efficiently. The goal of the program is to help patients find both quality and value for their specialty care needs, while providing a credible foundation on which employers may customize their employee benefits in local communities and nationwide.

### Blue Distinction Centers for Gene Therapy – Ocular Disorders

The Blue Distinction Centers for Gene Therapy program (Program) aims to improve patient outcomes and cost for members, beginning with ocular disorders (initially, including confirmed retinal dystrophy associated with a certain inherited genetic mutation). This Program focuses on a new gene therapy (Luxturna™), which has been approved by the FDA to treat patients with a specific type of inherited blindness. The treatment introduces a genetically modified healthy version of the gene and offers a new treatment option for certain patients where none existed in the past. The complexity and expertise needed to deliver this treatment supports identifying centers of excellence, through this Program. Providers whose program has been identified and publicly listed as qualified to provide ocular gene therapy (OGT), under the relevant OGT program of at least one manufacturer of an FDA approved OGT therapy, will be invited to participate in this Blue Distinction Program's evaluation process. The Program will continue to expand in the future, as new treatments become FDA approved.

Since gene therapy for this ocular disorder has been recently introduced into clinical use, current insight into the episode of care and optimal clinical pathway is limited. As the Blue Distinction Program and its selection criteria evolve, we will continue to work with the medical community to identify meaningful clinical measures of quality and establish outcomes data to guide quality improvement for patient care.

Designation as a Blue Distinction Center for Gene Therapy differentiates providers locally, as well as nationally. This highly respected designation acknowledges the expertise providers have demonstrated and their commitment to improving quality and affordability. Designations are awarded based on quality criteria that support delivery of timely, coordinated, multidisciplinary, evidence based care with a focus on quality improvement and patient-centered care. To be considered for the Blue Distinction Centers for Gene Therapy – Ocular Disorders designation, a provider must:

- meet Quality Criteria;
- meet Business Criteria;
- meet Value Criteria for specialty pharmacy product; and
- meet Local Blue Plan Criteria, if applicable.

## Quality Criteria

“**Ocular Gene Therapy (OGT) Episode of Care,**” as used herein, pertains to ocular gene therapy using an FDA-approved product (i.e., Luxturna), and includes: (1) pre-OGT evaluation, including genetic testing for RPE mutation status and testing to confirm eligibility (e.g., optical coherence tomography, ophthalmoscopy, and visual field testing); (2) OGT preparation, injection of one or both eyes, acute phase recovery, monitoring, and management; and (3) monitoring outcomes, managing any complications, and providing ongoing support during later phase follow up.

Blue Distinction Centers for Gene Therapy – Ocular Disorders		
Quality Criteria Category	Definition	Selection Criteria
Delivery	Accessibility to timely, multidisciplinary, coordinated ocular gene therapy (OGT) care.	1. Delivers efficient, appropriate, and effective flow of necessary patient care information to providers and patients (e.g., use of EHR and patient portal).
		2. Delivers care planning by managing patients throughout all stages of treatment during OGT Episode of Care.
		3. Facilitates multidisciplinary care (either within an integrated delivery system or through coordination within a virtually organized 'medical neighborhood' delivery system), to ensure that the patient has access to <b>all</b> of the following disciplines: <ul style="list-style-type: none"> <li>• Ophthalmology, including retinal surgery; and</li> <li>• Genetic counseling for inherited retinal diseases.</li> </ul>
Quality	Commitment to providing safe, evidence-based, patient-centered care	4. Ensures enhanced care access (open access scheduling, expanded hours, and new options for communication between patient and practice) to support urgent needs for patients under treatment at your facility.
		5. Provider’s program is identified and publicly listed as qualified to provide ocular gene therapy, under the relevant ocular gene therapy program of at least one manufacturer of an FDA approved OGT therapy.
		6. Implements patient-centered care by including patient/family in planning and goal setting, as well as managing symptoms, with the goal of improving quality of life for both the patient and the family.
	Commitment to measuring and improving quality of care for ocular gene therapy	7. Commits to standard practices and monitoring for safe administration of ocular gene therapy.
		8. Commits to system-wide monitoring and reporting of outcomes for ocular gene therapy patients through a registry, and to report requested quality measures to BCBSA to support designation evaluation.
		9. Incorporates measurement results into feedback and improvement of the ocular gene therapy system of care.

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Quality Criteria Category	Definition	Selection Criteria
Utility	Focuses on patient experience and patient engagement in shared decision making	10. Engages patient (family) in shared decision making process for goal setting and treatment planning that provides information on realistic expectations and impacts of treatment options, through use of appropriate tools, so that care delivers utility to the patient.
		11. Participates in a standardized Patient Satisfaction and Experience Survey to evaluate and improve care delivery.
Local Blue Plan Quality Criteria <sup>1</sup> (if applicable)	An individual Blue Plan, at its own independent discretion, may establish and apply local business requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.	

### Business Criteria

Blue Distinction Centers for Gene Therapy – Ocular Disorders	
Business Criteria Category	Selection Criteria
Facility Participation	All facilities are required to participate in the local Blue Plan's BlueCard Preferred Provider Organization (PPO) Network.
Physician Specialists Participation	All physician specialists (identified in the Provider Survey as those who perform the gene therapy for ocular disorders procedures at that facility) are required to participate in the local Blue Plan's BlueCard PPO Network <sup>2</sup> .
Blue Brands Criteria	Provider and its corporate family meet BCBSA criteria for avoiding conflicts with BCBSA logos and trademarks.
Local Blue Plan Business Criteria <sup>3</sup> (if applicable)	An individual Blue Plan, at its own independent discretion, may establish and apply local business requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.

<sup>1</sup> Local Blue Plan Quality Criteria may consist of additional quality criteria beyond the national criteria, at the discretion of the local Blue Plan.

<sup>2</sup> De Minimis Rule may be applied, at the local Blue Plan's discretion

<sup>3</sup> Local Blue Plan Business Criteria may consist of additional business criteria beyond the national criteria, at the discretion of the local Blue Plan.

## Value Criteria

In addition to meeting quality and business criteria, each provider is required to have a payment model for Gene Therapy for Ocular Disorder specialty pharmacy products with their local Blue Plan that meets the value criteria, which includes protection against mark-up over the wholesale acquisition cost (WAC).

Although a Blue Distinction Center+ (BDC+) designation is not offered at this time, the initial BDC designation incorporates an expectation of cost value; a BDC+ level designation may be added in a future designation enhancement, once episode based cost of care may be measured and risk adjusted meaningfully.

As the Program evolves for a re-designation cycle, targeted for 2021, a global episode based payment model including medical care services is anticipated to be added as an additional requirement.

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Value Criteria Category	Definition	Selection Criteria
Payment Model	Payment model with local Blue Plan for ocular gene therapy specialty pharmacy product meets the established value criteria.	<p>1. A case rate or global payment mechanism that includes both the product and episode of care.</p> <p align="center"><b>- OR -</b></p> <p>2. Establishment of a value based payment model that includes, but is not limited to, the following concepts:</p> <p><b>a.</b> Arrangements for the local Blue Plan to purchase ocular gene therapy Specialty Pharmacy Product directly from the manufacturer or through the Provider, without mark-up from the wholesale acquisition cost (WAC)*; <b>and</b></p> <p><b>b.</b> Incorporation of at least:</p> <ul style="list-style-type: none"> <li>• Additional discount off of WAC; <b>or</b></li> <li>• Acceptance of a warranty program or other outcomes based payment model from the manufacturer(s) of the ocular gene therapy Specialty Pharmacy Product (e.g., warranty or payment adjustment for unsuccessful patient outcome); <b>or</b></li> <li>• Another outcomes based payment model that is associated with both quality and cost outcomes that is developed and agreed by the Provider and local Blue Plan.</li> </ul> <p>* A Provider may not be disqualified from meeting the Value Criteria if its Local Plan payment arrangement: (1) incorporates a commercially reasonable service fee (e.g., “administrative” or “handling” fee) for Provider services associated with handling, storing, or administering the specialty pharmacy product; or (2) complies with local or state regulatory requirements regarding provider payment rates for specialty pharmacy products.</p>
<b>Local Blue Plan Value Criteria<sup>4</sup></b> <i>(if applicable)</i>	An individual Blue Plan, at its own independent discretion, may establish and apply local value requirements as additional Selection Criteria for eligibility in a Blue Distinction Centers program, for facilities located within its Service Area.	

<sup>4</sup> Local Blue Plan Value Criteria may consist of additional value criteria beyond the national criteria, at the discretion of the local Blue Plan.