

### What is Gene Therapy?

DNA is the blueprint, or genetic code, that lives inside each cell. Occasionally one of these genes mutates and malfunctions, leading to a genetic disorder. Gene therapy is a treatment designed to fix the genetic code by introducing a functioning copy of the misfiring gene into a patient.<sup>1</sup> The healthy copy repairs the faulty gene and restores its proper functioning.

In recent years, intensive research and development has led to remarkable advances in gene therapy. It holds the potential to cure many diseases once thought to be incurable, but these benefits may come with an extremely high price tag.

### Spotlight on Luxturna

One such gene therapy treatment is Luxturna, approved by the FDA in 2017 to treat a group of genetic eye conditions, called Inherited Retinal Disease (IRD), that can lead to vision loss and blindness. There are more than 250 different genes known to cause IRD. It is the leading cause of vision loss in people 15-45 years old.

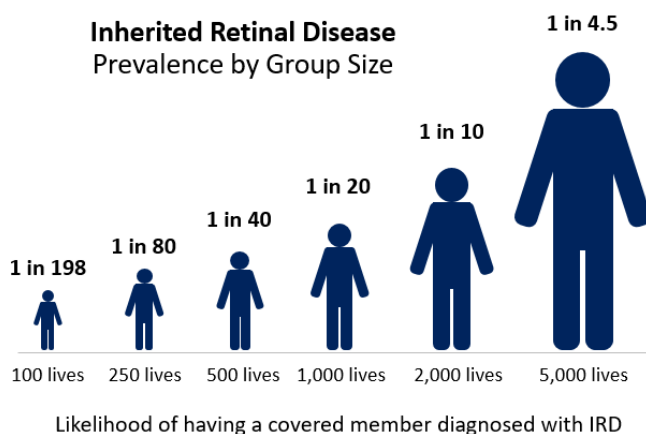
- Luxturna targets a specific mutation on the RPE65 gene and restores its ability to instruct the body to make a protein needed for normal vision.<sup>2</sup>
- Approximately 1,000-2,000 people in the U.S. have the RPE65 mutation.
- Luxturna is administered to patients under anesthesia as an injection beneath the retina. The first eye is treated, and then the second is treated at least 6 days later.

### Estimated Costs

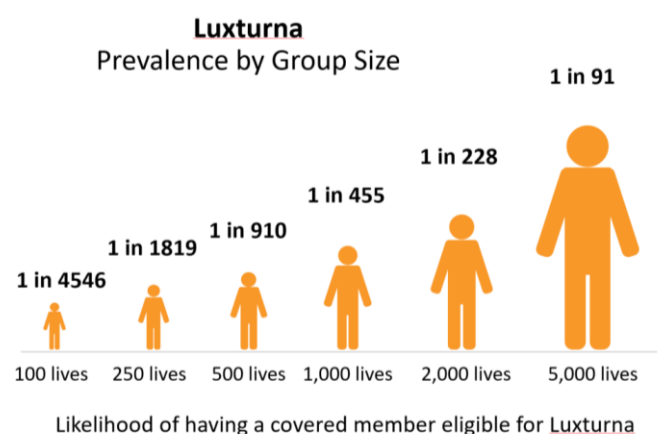
- Average cost of Luxturna: \$850,000
- Berkley Accident and Health has forged a relationship with Emerging Therapy Solutions (ETS) for a best-in-class service to positively manage gene therapy costs. **Estimated Luxturna savings with ETS: \$67,000<sup>2</sup>**

### Risk for Self-Funded Groups

For self-funded groups, the likelihood of having a Luxturna claim increases as the group size grows. Additionally, there is no required testing which causes the RPE65 mutation to go largely undiagnosed. If testing were to become more widely used, those individuals that are Luxturna eligible will increase.



Assumes each enrolled employee represents 2.2 members and the birth rate per employee is consistent with the national average. Likelihood is defined as the percentage chance in any calendar year.  
Source: Emerging Therapy Solutions, <https://emergingtherapies.com/>



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## Financial Challenges on the Horizon

Gene therapies like Luxturna and their associated high price tags are poised to change the health care landscape this decade. In early 2020, the FDA introduced a number of policies that will allow it to fast-track gene therapy approvals. By 2025, the agency expects it will be reviewing and approving between 10 to 20 gene and cell therapies each year.<sup>3</sup>

This trend may present challenges to self-funded employers, including the potential for increases to their Stop Loss premiums and/or greater frequency of higher individual deductibles (“lasering”). Due to these challenges, as well as the possibility of an unaffordable high-dollar claim, partnering with their Stop Loss carrier will be more important than ever to safeguard their plan’s financial health.

### Berkley Accident and Health and Emerging Therapy Solutions (ETS)

Berkley Accident and Health is closely monitoring the gene therapy market and has a demonstrated track record of helping lower costs for all types of catastrophic claims on behalf of our clients. We’re actively developing solutions to support our policyholders, including our relationship with Emerging Therapy Solutions (ETS) for cell and gene therapy pricing solutions and data analytics. With our expertise and financial strength, clients can have confidence in Berkley Accident and Health. For more information, contact your Berkley Accident and Health representative.

Through Berkley Accident and Health’s relationship with ETS, policyholders can positively impact the cost of gene therapy treatments.



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Prevalence of IRD and Luxturna assumes each enrolled employee represents 2.2 members and the birth rate per employee is consistent with the national average. Likelihood is defined as the percentage change in any calendar year.

Berkley Accident and Health has used specific data collected by Emerging Therapy Solutions (ETS). However, Berkley Accident and Health assumes no responsibility or liability for any advice or resources provided by ETS.

This content is for general informational purposes only; it is not legal advice or a legal opinion. You should seek the advice of legal and tax counsel before acting upon any of this information. In addition, you should perform your own due diligence on any potential vendor or solution.

<sup>1</sup>U.S. National Library of Medicine, *How does Gene Therapy Work*, <https://ghr.nlm.nih.gov/primer/therapy/procedures>

<sup>2</sup>Emerging Therapy Solutions, <https://emergingtherapies.com/>

<sup>3</sup>U.S. Food & Drug Administration, *FDA Continues Strong Support of Innovation in Development of Gene Therapy Products*, <https://www.fda.gov/news-events/press-announcements/fda-continues-strong-support-innovation-development-gene-therapy-products>  
All information accessed October 2020.

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