

| PA Criteria                                   | Criteria Details                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
|-----------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|----------------|--------------|---------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|-------|-------------------------------------------|----------------------|-------------|-------|---------------------------------------------------------------------------------------------|
| <b>Description</b>                            | ENCELTO™ is an allogeneic encapsulated cell-based gene therapy; it is an intravitreal implant that releases recombinant human ciliary neurotrophic factor (rhCNTF).                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
| <b>Covered Uses (FDA approved indication)</b> | ENCELTO is indicated for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
| <b>Dosing and Administration</b>              | <table border="1"> <thead> <tr> <th>Indication</th> <th>Dosing Regimen</th> <th>Maximum Dose</th> </tr> </thead> <tbody> <tr> <td>MacTel Type 2</td> <td>One single-dose implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)<br/><br/>Administration: ENCELTO implant insertion is a <i>surgical procedure</i> performed in an operating room under aseptic conditions by a qualified ophthalmologist.</td> <td>Single dose per affected eye per lifetime</td> </tr> </tbody> </table>                                                               | Indication                                | Dosing Regimen | Maximum Dose | MacTel Type 2 | One single-dose implant per affected eye containing 200,000 to 440,000 allogeneic retinal pigment epithelial cells expressing rhCNTF (NTC-201-6A cell line)<br><br>Administration: ENCELTO implant insertion is a <i>surgical procedure</i> performed in an operating room under aseptic conditions by a qualified ophthalmologist. | Single dose per affected eye per lifetime |       |                                           |                      |             |       |                                                                                             |
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| <b>Billing and Coding Information</b>         | <table border="1"> <thead> <tr> <th>10-digit NDC</th> <th>11-digit NDC</th> </tr> </thead> <tbody> <tr> <td>82958-501-01</td> <td>82958-0501-01</td> </tr> </tbody> </table><br><table border="1"> <thead> <tr> <th>HCPCS Code</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>J3403</td> <td>Revakinagene taroretcel-lwey, per implant</td> </tr> </tbody> </table><br><table border="1"> <thead> <tr> <th>CPT Procedural Codes</th> <th>Description</th> </tr> </thead> <tbody> <tr> <td>67027</td> <td>Implantation of intravitreal drug delivery system, includes concomitant removal of vitreous</td> </tr> </tbody> </table> | 10-digit NDC                              | 11-digit NDC   | 82958-501-01 | 82958-0501-01 | HCPCS Code                                                                                                                                                                                                                                                                                                                          | Description                               | J3403 | Revakinagene taroretcel-lwey, per implant | CPT Procedural Codes | Description | 67027 | Implantation of intravitreal drug delivery system, includes concomitant removal of vitreous |
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| 82958-501-01                                  | 82958-0501-01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
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| J3403                                         | Revakinagene taroretcel-lwey, per implant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
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| <b>Product Availability</b>                   | <i>Single-dose Intravitreal Implant, Sterile:</i> 200,000 – 440,000 cells per implant                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |
| <b>Contraindications</b>                      | <ul style="list-style-type: none"> <li>Ocular or periocular infections</li> <li>Known hypersensitivity to Endothelial Serum Free Media (Endo-SFM)</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                           |                |              |               |                                                                                                                                                                                                                                                                                                                                     |                                           |       |                                           |                      |             |       |                                                                                             |

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|----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Recommended Medical Monitoring</b></p> | <p>ENCELTO implantation has been associated with:</p> <ul style="list-style-type: none"> <li>• Severe Vision Loss (defined as <math>\geq</math> three lines of visual acuity loss)</li> <li>• Infectious Endophthalmitis</li> <li>• Retinal Tear and Detachment</li> <li>• Vitreous Hemorrhage             <ul style="list-style-type: none"> <li>» Increased risk in patients receiving antithrombotic medications (e.g. oral anticoagulants, aspirin, NSAIDs); must stop use prior to implantation</li> </ul> </li> <li>• Implant Extrusion</li> <li>• Cataract Formation</li> <li>• Suture Related Complications</li> <li>• Delayed Dark Adaptation</li> </ul> <p>Patients should be instructed to report any signs/symptoms that could be associated with these events. Additional surgical and/or medical management may be required.</p> |
| <p><b>Approval Criteria</b></p>              | <ul style="list-style-type: none"> <li>a. Physician administered Intravitreal implant; administered surgically (ambulatory surgery center)             <ul style="list-style-type: none"> <li>i. Cannot be self-administered</li> </ul> </li> <li>b. <b>MacTel Type 2 (must meet all):</b> <ul style="list-style-type: none"> <li>i. Diagnosis of MacTel Type 2 in at least one eye</li> <li>ii. Age <math>\geq</math> 18 years</li> <li>iii. Prescribed by and under care of qualified ophthalmologist</li> <li>iv. Maximum one treatment per eye per lifetime</li> <li>v. Patient will be monitored for signs/symptoms of retinal tears and/or retinal detachment (e.g., acute onset off flashing lights, floaters, and/or loss of visual acuity)</li> </ul> </li> </ul>                                                                     |
| <p><b>Age Restriction</b></p>                | <p>Adults <math>\geq</math> 18 years old.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <p><b>Coverage Duration</b></p>              | <p>Approval Duration: two months (one implant per eye per lifetime)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |

| STATUS  | DATE REVISED | REVIEW DATE | APPROVED/REVIEWED BY                          | EFFECTIVE DATE |
|---------|--------------|-------------|-----------------------------------------------|----------------|
| Created | 9/17/2025    | 9/17/2025   | Tamara Chinarian, PharmD, Clinical Pharmacist | N/A            |
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