

PA Criteria	Criteria Details						
<b>Covered Uses (FDA approved indication)</b>	Lyfgenia is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.						
<b>Exclusion Criteria</b>	Lyfgenia is not covered in patients with prior HSCT or prior gene therapy.						
<b>Required Medical Information</b>	<p>Before the drug is covered, the patient must meet the following requirements:</p> <ol style="list-style-type: none"> <li>1. Patient has a diagnosis of Sickle Cell Disease (SCD) with <math>\beta\text{S}/\beta\text{S}</math>, <math>\beta\text{S}/\beta\text{O}</math>, or <math>\beta\text{S}/\beta+</math> genotype confirmed by genetic testing;</li> <li>2. Patient has a history of at least four severe vaso-occlusive events within the previous two years;</li> <li>3. Patient's current weight has been provided;</li> <li>4. Patient has adequate organ function and is eligible for HSCT (stem cell transplant);</li> <li>5. Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment;</li> <li>6. Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine).</li> </ol>						
<b>Age Restriction</b>	Patient is at least 12 years of age.						
<b>Prescriber Restrictions</b>	Must be prescribed by or in consultation with a hematologist or other clinically appropriate provider.						
<b>Coverage Duration</b>	Six months authorization duration with a limit of one dose (treatment) per lifetime.						
<b>Other Criteria/Information</b>	<p>Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.</p> <table border="1"> <thead> <tr> <th>HCPCS</th> <th>Description</th> <th>Billing Units/How Supplied</th> </tr> </thead> <tbody> <tr> <td>J3394</td> <td>Lyfgenia (lovotibeglogene autotemcel)</td> <td> <b>Billing unit: per therapy</b>   <math>f 3 \times 10^6</math> CD34+ cells/kg of body weight, in one to four infusion bags. </td> </tr> </tbody> </table>	HCPCS	Description	Billing Units/How Supplied	J3394	Lyfgenia (lovotibeglogene autotemcel)	<b>Billing unit: per therapy</b>  $f 3 \times 10^6$ CD34+ cells/kg of body weight, in one to four infusion bags.
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STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	5/15/2025	Pharmacy & Therapeutics (P&T) Committee	5/15/2025