

PA Criteria	Criteria Details
<b>Covered Uses (FDA approved indication)</b>	Casgevy is indicated for the treatment of patients 12 years of age and older with: Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) transfusion-dependent $\beta$ -thalassemia (TDT).
<b>Exclusion Criteria</b>	Casgevy is not covered in patients with prior HSCT or prior gene therapy.
<b>Required Medical Information</b>	<p><b>FOR SICKLE CELL REQUESTS:</b> Before the drug is covered, the patient must meet the following requirements: Medical records supporting the request must be provided; AND 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; AND Patient has a history of at least two severe vaso-occlusive events per year in the previous two years; AND Patient's current weight has been provided; AND Patient has adequate organ function and is eligible for HSCT (stem cell transplant); AND Patient does not have a contraindication to any product or procedure required for successful gene therapy treatment; AND Patient has tried and failed hydroxyurea, or if not tolerated, at least one other SCD treatment such as Endari (L-Glutamine).</p> <p><b>FOR BETA THALESSEMIA REQUESTS:</b> Before the drug is covered, the patient must meet the following requirements: Medical records supporting the request must be provided; AND Must have a diagnosis of transfusion dependent beta thalassemia (defined as a history of at least 100 mL/kg/year or 10 units/year of packed red blood cells (pRBC) in the previous two years); AND Must not have a known and available HLA matched donor as determined by the hematologist and/or transplant specialist; AND Provider attests that, in the absence of a known or available HLA-matched family donor, the patient would be otherwise clinically stable and eligible to undergo HSCT.</p>
<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.

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Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.		
	HCPCS	Description	Billing Units/How Supplied
	J3392	Casgevy (exagamglogene autotemcel)	<b>Billing unit: per treatment</b>  3 × 10 <sup>6</sup> CD34+ cells per kg of body weight, which may be composed of multiple vials.

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