PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Lovotibeglogene autotemcel (e.g., Lyfgenia)	2024014	Coverage criteria update. Criteria regarding allogeneic stem cell transplant exclusion were edited to reflect human leukocyte antigen matching status. 1. Individual is at least 12 years of age (Lyfgenia, 2023); **AND** 2. Individual has a documented diagnosis of sickle cell disease confirmed by testing demonstrating one of the following (Lyfgenia, 2023): a. Homozygous sickle cell disease (e.g., HbSS); **OR** b. Heterozygous sickle cell disease (e.g., HbSC, HbSBeta+, HbSBeta0, HbSD, HbSOArab, HbSE); **AND** 3. Individual has a history of recurrent vaso-occlusive crises (VOCs) as evidenced by greater than or equal to 4 severe VOC(s) in the most recent 24 months (see policy guidelines for a definition of VOC) (Lyfgenia, 2023); **AND** 4. *Applicable only to individuals less than 18 years of age:* Individual does not have an available and willing matched HLA-identical sibling hematopoietic cell donor (Kanter, 2022) (Kassim 2024); **AND** 5. Individual has not received allogenic hematopoietic stem cell transplant (Lyfgenia, 2023); **AND** 6. Individual meets the institutional requirements for a stem cell transplant procedure where the individual is expected to receive gene therapy (see policy guidelines): a. Adequate Karnofsky performance status or Lansky performance status b. Absence of advanced liver disease c. Adequate estimated glomerular filtration rate (eGFR)	No	1/28/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024014

		d. Adequate diffusing capacity of the lungs for carbon monoxide (DLCO) e. Adequate left ventricular ejection fraction (LVEF) f. Absence of clinically significant active infection(s) 7. Individual does not have a history of receiving gene therapy or under consideration for treatment for another gene therapy for sickle cell disease; **AND** 8. Individual does not have any of the following: a. Any prior or current malignancy or immunodeficiency disorder; **OR** b. Any immediate family member with a known or suspected Familial Cancer Syndrome (including but not limited to hereditary breast and ovarian cancer syndrome, hereditary non-polyposis colorectal cancer syndrome, and familial adenomatous polyposis).			
Exagamglogene autotemcel (e.g., Casgevy)	2024013	Coverage criteria updated. Criteria regarding allogeneic stem cell transplant exclusion were edited to reflect human leukocyte antigen matching status for Sickle Cell Disease and Beta thalassemia. Sickle Cell Disease: 1. Individual is at least 12 years of age (Casgevy, 2024); **AND** 2. Individual has a documented diagnosis of sickle cell disease confirmed by testing demonstrating the following (Casgevy, 2024): a. Homozygous sickle cell disease (e.g., HbSS); **OR** b. Heterozygous sickle cell disease (e.g., HbSC, HbSBeta+, HbSBeta0, HbSD, HbSOArab, HbSE); **AND** 3. Individual has a history of recurrent vaso-occlusive crises (VOCs), as evidenced by greater than or equal to 4 severe VOC(s) in	No	1/28/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024013

		the most recent 24 months (see policy guidelines for a definition of VOC); **AND** 4. *Applicable only to individuals less than 18 years of age:* Individual does not have a known 10/10 human leukocyte antigen (HLA) matched related donor willing to participate in an allogeneic (Frangoul, 2023) (Kassim 2024); **AND** 5. Individual has not received allogenic hematopoietic stem cell transplant (Casgevy, 2024); **AND** 6. Individual meets the institutional requirements for a stem cell transplant procedure where the individual is expected to receive gene therapy (see policy guidelines): a. Adequate Karnofsky performance status or Lansky performance status b. Absence of advanced liver disease c. Adequate estimated glomerular filtration rate (eGFR) d. Adequate diffusing capacity of the lungs for carbon monoxide (DLCO) e. Adequate left ventricular ejection fraction (LVEF) f. Absence of clinically significant active infection(s) 7. Individual does not have a history of receiving gene therapy or is not under consideration for treatment with another gene therapy for sickle cell disease. Beta Thalassemia: 1. Individual is at least 12 years of age (Casgevy, 2024); **AND** 2. Individual has a documented diagnosis of Beta-thalassemia as evidenced by one of the following genotypes by globin gene testing (Casgevy, 2024): a. Beta0/Beta0; **OR** b. Beta0/Beta0 – like (see policy guidelines); **OR** c. Non-Beta0/Beta0 (see policy guidelines); **AND**			

		3. Individual requires regular peripheral blood transfusions to maintain target hemoglobin levels as defined by documentation of the following: a. History of receiving transfusions of greater than or equal to 100 ml per kilogram of body weight of packed red blood cells per year; **OR** b. History of receiving greater than or equal to 8 transfusions per year in the prior 2 years at the time of treatment decision (Frangoul, 2023; Locatelli, 2022); **AND** 4. *Applicable only to individuals less than 18 years of age:* Individual does not have a known 10/10 human leukocyte antigen (HLA) matched related donor willing to participate in an allogeneic (Frangoul, 2023) (Kassim 2024); **AND** 5. Individual has not received allogenic hematopoietic stem cell transplant (Casgevy, 2024); **AND** 6. Individual meets the institutional requirements for a stem cell transplant procedure where the individual is expected to receive gene therapy (see policy guidelines): a. Adequate Karnofsky performance status or Lansky performance status b. Absence of advanced liver disease c. Adequate estimated glomerular filtration rate (eGFR) d. Adequate diffusing capacity of the lungs for carbon monoxide (DLCO) e. Adequate left ventricular ejection fraction (LVEF) f. Absence of clinically significant active infection(s) 7. Individual does not have a history of receiving gene therapy or is not under consideration for treatment with another gene therapy for beta thalassemia.			