Policy Number	RX501.071
Policy Effective Date	02/01/2025

Plerixafor for Non-Oncologic Indications

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Related Policies (if applicable)
RX501.148: Betibeglogene autotemcel
RX501.166: Exagamglogene autotemcel
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RX502.061: Oncologic Medications

Disclaimer

Medical policies are a set of written guidelines that support current standards of practice. They are based on current peer-reviewed scientific literature. A requested therapy must be proven effective for the relevant diagnosis or procedure. For drug therapy, the proposed dose, frequency and duration of therapy must be consistent with recommendations in at least one authoritative source. This medical policy is supported by FDA-approved labeling and/or nationally recognized authoritative references to major drug compendia, peer reviewed scientific literature and acceptable standards of medical practice. These references include, but are not limited to: MCG care guidelines, DrugDex (IIa level of evidence or higher), NCCN Guidelines (IIb level of evidence or higher), NCCN Compendia (IIb level of evidence or higher), professional society guidelines, and CMS coverage policy.

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

NOTE 1: This policy does not address the oncologic indications for Plerixafor (Mozobil®). Refer to RX502.061 Oncology Medications for the use of Plerixafor (Mozobil®) for oncologic indications.

Plerixafor (Mozobil®) **may be considered medically necessary** for non-oncologic indications when used in combination with other therapies when **ALL** the following criteria are met:

- The individual meets criteria for approval of the primary therapy (i.e., betibeglogene autotemcel [Zynteglo®], OR lovotibeglogene autotemcel [Lyfgenia®], OR exagamglogene autotemcel [Casgevy™]); **AND**

- The prescribing information of the primary therapy (i.e., betibeglogene autotemcel [Zynteglo®], OR lovotibeglogene autotemcel [Lyfgenia®], OR exagamglogene autotemcel [Casgevy™]) indicates that plerixafor (Mozobil®) is necessary for the administration of the primary therapy.

Policy Guidelines

None.

Description

Plerixafor (Mozobil®) is a hematopoietic stem cell mobilizer and inhibitor of the C-X-C chemokine receptor type 4 (CXCR4). CXCR4 is specific for stromal-derived-factor-1 (SDF-1), a molecule endowed with potent chemotactic activity for lymphocytes. Because the interaction between SDF-1 and CXCR4 plays an important role in holding hematopoietic stem cells in the bone marrow, drugs that block the CXCR4 receptor appear to be capable of "mobilizing" hematopoietic stem cells into the bloodstream.

Mozobil, in combination with granulocyte-colony stimulating factor (G-CSF), is specifically indicated to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients.

Mobilization and Apheresis Prior to Administration of Gene Therapies
Prior to the administration of the gene therapies approved for sickle cell disease or beta-thalassemia, individuals are required to undergo a mobilization and apheresis process to obtain CD34+ cells for product manufacturing.

Betibeglogene autotemcel (Zynteglo®)
The target number of CD34+ cells to be collected is ≥ 12×10^6 CD34+ cells/kg. If the minimum dose of 5.0×10^6 CD34+ cells/kg is not met, the patient may undergo additional cycles of mobilization and apheresis, separated by at least 14 days, in order to obtain more cells for additional manufacture. Granulocyte-colony stimulating factor (G-CSF) and plerixafor were used for mobilization and busulfan was used for myeloablative conditioning. All patients were administered G-CSF and plerixafor to mobilize stem cells prior to the apheresis procedure. The planned dose of G-CSF was 10 µg/kg/day in patients with a spleen, and 5 µg/kg/day in patients without a spleen, given in the morning on Days 1 through 5 of mobilization. The planned dose of plerixafor was 0.24 mg/kg/day, given in the evening on Days 4 and 5 of mobilization. Apheresis generally occurred on mobilization Day 5 and 6 and if a third day of collection was needed, plerixafor and G-CSF dosing was extended to Day 6. The dose of G-CSF was decreased by half if the white blood cell (WBC) count exceeded 100×10^9/L prior to the day of apheresis. Most patients collected the minimum number of CD34+ cells to manufacture ZYNTEGLO with 1 cycle of mobilization and apheresis. (1)

Lovotibeglogene autotemcel (Lyfgenia®)

Administer plerixafor to mobilize stem cells prior to the apheresis procedure at a dose of 0.24 mg/kg/day. Begin apheresis approximately 4 to 6 hours after plerixafor administration. If more than one apheresis day is required, confirm platelet counts to be ≥ 75×10^9/L within 24 hours of subsequent apheresis sessions, prior to administration of plerixafor on that day. If platelet counts do not meet these criteria, defer mobilization and apheresis until the platelet counts recover to ≥ 75×10^9/L. For patients undergoing more than 1 mobilization cycle, separate each cycle by at least 14 days. Administer daily plerixafor 4 to 6 hours prior to each apheresis collection. If a sufficient number of cells are collected after the first mobilization cycle, no further mobilization/apheresis is required. In clinical studies, the minimum number of CD34+ cells to manufacture Lyfgenia was collected in most patients with 1 or 2 cycles of mobilization and apheresis, which typically required 2 consecutive collection days per cycle. Maximize CD34+ cell collection to obtain as many CD34+ stem cells as possible for product manufacturing during each mobilization and apheresis cycle. Target a minimum collection of 16.5×10^6 CD34+ cells/kg for manufacturing and back-up. If, after manufacturing, the minimum dose of 3×10^6 CD34+ cells/kg is not achieved, the patient may undergo additional cycles of mobilization and apheresis, separated by at least 14 days, to obtain more cells for additional manufacture. (2)

Exagamglogene autotemcel (Casgevy™)

Plerixafor was used for mobilization. Granulocyte-Colony Stimulating Factor (G-CSF) should not be administered for mobilization in patients with sickle cell disease. Maximize CD34+ cell collection to obtain as many CD34+ cells as possible for product manufacturing during each mobilization and apheresis cycle. Perform two consecutive days of cell collection for product manufacturing per cycle, if clinically tolerated. A total collection target of at least 20×10^6 CD34+ cells/kg is recommended for product manufacture. Collected cells should be sent for product manufacturing even if the total collection target is not achieved. In addition, at least 2×10^6 CD34+ cells/kg is required to be collected for back-up unmodified rescue cells. A third day of cell collection can be used to obtain back-up rescue cells, if needed. If the minimum dose of Casgevy (3×10^6 CD34+ cells/kg) is not met after initial product manufacturing, the patient will need to undergo additional cycles of mobilization and apheresis. Each mobilization and apheresis cycle must be separated by a minimum of 14 days. (3)

Regulatory Status

Plerixafor (Mozobil®, Genzyme Corp, MA) was approved in 2008 by the U.S. Food and Drug Administration (FDA) to be used in combination with filgrastim to enhance mobilization hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma. In 2003, it was given orphan drug designation for use to improve the yield of progenitor cells in the apheresis product for subsequent stem cell transplantation following myelosuppressive or myeloablative chemotherapy. (4, 5)

This policy does not address the oncologic indications for Plerixafor (Mozobil®). Refer to RX502.061 Oncology Medications for the use of Plerixafor (Mozobil®) for oncologic indications.

Rationale

This policy was developed in September 2024 and is based on a review of the literature in the PubMed database as of September 11, 2024.

In 2020, Tisdale et al. reported on a multi-center, phase 1-2 study (NCT02140554) of LentiGlobin™ Drug Product (DP) in adults with severe sickle cell disease (SCD). (6) They collected autologous CD34+ cells by bone marrow harvest (BMH) or by mobilization with plerixafor 240 µg/kg and apheresis for transduction with the LentiGlobin BB305 vector and for back-up in the event of graft failure. Patients underwent myeloablation with busulfan before infusion with the transduced cells and were then monitored for engraftment, safety and efficacy. As of July 21, 2017, 9 patients with severe SCD received LentiGlobin DP manufactured using autologous CD34+ cells collected through BMH. An additional 3 patients had CD34+ cells collected after plerixafor mobilization and apheresis, including 1 patient who also had a BMH. A mean of 5.0 (range 0.3-10.8) × 10^6 CD34+ cells/kg were collected per BMH (N = 21 harvests). Eighteen grade 3 adverse events (AEs) in 6 patients were attributed to BMH: pain (n = 12), anemia (n = 3), and vaso-occlusive crisis (VOC) (n = 3). Following plerixafor administration, apheresis collected 15.3, 5.6, and 9.0 × 10^6 CD34+ cells/kg (1 cycle each). A transient 1.5- to 3-fold increase in peak white blood count (WBC) and absolute neutrophil count (ANC) levels was observed. Peak absolute CD34+ cell counts in peripheral blood (PB) were 170, 58, and 160 × 10^6 cells/L. No dose-limiting toxicities were observed after plerixafor 240 µg/kg. Two patients experienced a single grade 3 adverse events (AE) attributed to apheresis or mobilization: hypomagnesemia resolved in one day and a VOC resolved in 5 days (this patient also experienced a VOC after BMH). The authors concluded that plerixafor mobilization and apheresis appears to be a suitable alternative to BMH for CD34+ cell harvesting in autologous HSC gene therapy for patients with severe SCD. In contrast to reported granulocyte-colony stimulating factor (G-CSF) cases, they observed no life-threatening VOCs after plerixafor mobilization.

In an on-going open-label phase 1-2 trial (HGB-206, NCT02140554), Tisdale et al. (2020) evaluated the safety and efficacy of LentiGlobin (a drug product [DP] containing autologous CD34+ HSPCs transduced with BB305 lentiviral vector [LVV] encoding human β-globin gene with anti-sickling $\beta^{A\text{-}T87Q}$) in patients with SCD. (7) Patients were initially treated with DP made from BM-harvested HSPCs using the original (Group A) and then refined (Group B), manufacturing process. In Group C, patients received DPs made from plerixafor-mobilized HSPCs. Hydroxyurea was discontinued ≥30 days pre-cell collection (all patients). A transfusion regimen (Hb target of 10 g/dL and HbS <30%) was instituted about 60 days pre-HSPC collection in Groups B and C. Multiple BMHs (total nucleated cell target/BMH of ≥6 × 10^8/kg) and mobilization cycles (≤2 consecutive apheresis days/cycle separated by ≥14 days; total target of ≥10 × 10^6 CD34+ cells/kg, with 1.5 × 10^6 CD34+ cells/kg reserved for rescue) were permitted. As of September 14, 2018, Groups A and B completed enrollment; 11 patients (9 in Group A, 2 in Group B) underwent BMH. Group C enrollment was ongoing, and 14/18 enrolled patients had initiated

mobilization/apheresis. Given Group B patient 1 also underwent plerixafor mobilization/apheresis (for research purposes), the total of patients who had mobilization/apheresis was 15. Overall, 11/11 (100%) and 7/15 (47%) patients had an adverse event (AE) attributed to BMH and plerixafor mobilization/apheresis, respectively. Within 7 days of BMH, ≥Grade 3 AEs were reported in 55% of patients, including procedural pain (55%; deemed serious in 2 patients), vaso-occlusive pain (18%; considered serious), and anemia and postoperative anemia (9% each). These events were attributed to BMH, and all patients recovered without sequelae. Seven days post-BMH and through conditioning, 2 additional patients (from 9 who received DP following BMH) had ≥Grade 3 vaso-occlusive pain events. Postmobilization/apheresis, 4/15 patients (27%) had ≥ Grade 3 AEs within 7 days after last plerixafor administration; 3 of these (20%) reported serious vaso-occlusive pain attributed to mobilization/apheresis. These 3 serious AEs occurred within 2 days, post-plerixafor mobilization/apheresis, and resolved within 5 days. Three patients were reported to have hypomagnesemia (2 Grade 1, 1 Grade 3), and two had hypocalcemia (1 Grade 1, 1 Grade 2) within 7 days of plerixafor mobilization/apheresis.

Table 1. Adverse Events Associated with BMH or Plerixafor Mobilization/Apheresis

	BMH Group A and Group B N=11	**Plerixafor Mobilization/Apheresis Group B[a] and Group C N=15**
Number of BMH procedures	26	NA
Number of mobilization/apheresis cycles	NA	23
	N (%)	N (%)
Any AE within 1 day	11 (100)	8 (53.3)
≥Grade 3 events	6 (54.5)	3 (20.0)
Serious AEs	1 (9.1)	2 (13.3)
Any AE within 7 days	11 (100)	9 (60.0)
≥Grade 3 AEs	6 (54.5)	4 (26.7)
Serious AEs	3 (27.3)	3 (20.0)
AEs attributed to cell collection procedures at any time after cell collection	11 (100)	7 (46.7)

Adapted from Tisdale et al. (2020) (7).

AE: adverse event(s); BMH: bone marrow harvest.

[a] 1 patient in Group B had HSPC's isolated by both collection methods.

A median of 2 BMH procedures were performed per patient to collect sufficient cells for DP manufacturing. Six patients had 2 BMHs, 1 patient had 1 BMH, 3 patients had 3 procedures, and 1 patient had 4 BMH procedures to obtain enough cells. Repetitive BMH procedures amplify the potential risks associated with prolonged general anesthesia in a prone position and predispose the patient to regional hypoxia that promotes vaso-occlusion. A median of 1 plerixafor mobilization cycle with 2 apheresis procedures was sufficient for DP manufacturing and rescue aliquots. No patient required more than 2 mobilization cycles for DP manufacturing. One

patient in Group C had 3 mobilization cycles because the initial plerixafor mobilization and apheresis was reserved for rescue HSPC collection only. The rescue harvest was performed before this patient was assigned to Group C, after which 2 additional mobilization cycles were performed for DP manufacturing. Eight patients (53%) had a single mobilization cycle with 1–2 apheresis procedures needed to collect sufficient cells for transduction. Six patients had 2 mobilization cycles with 1–2 apheresis procedures per cycle. Plerixafor was expected to accomplish HSPC mobilization in patients with SCD without the degree of leukocytosis or neutrophil activation observed with G-CSF that could elicit vaso-occlusion and adverse clinical events. One patient who had Cycle 3 had baseline WBC of $20.7x10^9$/L on the first day of apheresis followed by an increase to $41.0x10^9$/L within 1 hour of apheresis. WBC was maintained at about 38–$49x10^9$/L through Day 2. ANC in Cycle 3 was $14.8x10^9$/L at baseline, peaked at $38.6x10^9$/L during apheresis of Day 1, and was at $33.2x10^9$/L 24 hours after plerixafor mobilization on the last day of apheresis. (7)

In 2018, Boulad et al. reported on a phase 1 dose-escalation study (NCT02193191) of plerixafor to evaluate the safety and efficacy of standard dosing on peripheral blood CD34+ cell mobilization. (8) Of the 15 patients enrolled, one was chronically transfused and 10 were on hydroxyurea. Of 8 patients who achieved a CD34+ cell concentration of >30 cells/µL, six were on hydroxyurea. There was no clear dose response to increasing plerixafor dosage. There was a low rate of serious adverse events with two patients developing vaso-occlusive crises at the doses of 80 µg/kg and 240 µg/kg. Hydroxyurea may have contributed to the limited CD34+ mobilization by affecting baseline peripheral blood CD34 counts, which correlated strongly with peak peripheral blood CD34 counts. The target goal of mobilizing at least 30 CD34+ cells/µL was reached in only 50% of patients given the plerixafor dose of 80 µg/kg, 67% of patients given 160 µg/kg, and 67% of patients given 240 µg/kg. Nine of fifteen patients (60%) with SCD treated with plerixafor reached the peripheral blood CD34 cell target count of at least 30 CD34+ cells/µL, including four of six patients treated at a dose of 240 µg/kg.

In a nonrandomized pilot safety and efficacy study (NCT02989701), Esrick et al. (2018) reported on plerixafor when used in transfused patients with SCD for HSC mobilization. (9) Six adult patients with SCD were recruited to receive a single dose of plerixafor, tested at lower than standard (180 mg/kg) and standard (240 mg/kg) doses, followed by CD34+ cell monitoring in peripheral blood and apheresis collection. The procedures were safe and well-tolerated. Mobilization was successful, with higher peripheral CD34+ cell counts in the standard vs. the low-dose group. Among the 6 donors, they improved apheresis cell collection results by using a deep collection interface and starting apheresis within 4 hours after plerixafor administration. In the subjects who received a single standard dose of plerixafor and followed the optimized collection protocol, yields of up to 24.5 X 10^6 CD34+ cells/kg were achieved. The collected CD34+ cells were enriched in immunophenotypically defined long-term HSCs and early progenitors. The authors demonstrated that plerixafor can be employed safely in patients with SCD to obtain sufficient HSCs for potential use in gene therapy.

Lagrsle-Peyrou et al. (2018) reported on an open-label phase 1-2 trial (NCT02212535) designed to demonstrate the safety and efficacy of the mobilization and harvesting of peripheral HSPC

following a single injection of 0.24 mg/kg plerixafor in 3 adult SCD patients. (10) The trial was restricted to patients with <$10x10^9$ granulocytes/L. Hydroxyurea was discontinued in one patient 3 months before the mobilization; and the patient underwent monthly transfusions until mobilization. The authors report rapid mobilization with plerixafor, with peak counts of over 80 CD34+/µL being achieved as early as 2-3 hours after plerixafor administration. They noted a decrease in CD34+ cell count after 6 hours and thought it could be the result of a short-term mobilization of HSC by plerixafor and therefore to the reduced egress of CD34+ cells from bone marrow combined with their return to the bone marrow. They also thought the drop was due to the leukapheresis procedure. The authors concluded that CD34+ cells can be safely mobilized with plerixafor in SCD patients under well-defined clinical conditions, including a 3-month interruption of hydroxyurea treatment, monthly transfusions, and red blood cell exchanges.

Summary of Evidence

No randomized controlled clinical trials were identified that provided information on the use of plerixafor (Mozobil®) for mobilization of hematopoietic stem cells in individuals with sickle cell disease. The U.S. Food and Drug Administration (FDA) provided an orphan drug designation for plerixafor for use to improve the yield of progenitor cells in the apheresis product for subsequent stem cell transplantation following myelosuppressive or myeloablative chemotherapy. Plerixafor has been studied in phase 1-2 clinical trials for the gene therapy products approved for treatment of sickle cell disease with good results. Plerixafor (Mozobil®) may be considered medically necessary in preparation for OR in combination with non-oncologic therapies such as betibeglogene autotemcel (Zynteglo®), lovotibeglogene autotemcel (Lyfgenia®), and exagamglogene autotemcel (Casgevy™) when those therapies meet criteria for approval.

Summary of Key Trials

Currently ongoing and unpublished trials that may influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Title	Planned Enrollment	Completion Date
Ongoing			
NCT03664830	A Pilot Study To Evaluate The Safety And Feasibility of Hematopoietic Progenitor Cell Mobilization With Plerixafor as Part of a Gene Therapy Strategy in Sickle Cell Disease	12	Sept 2024 (recruiting)
NCT02193191	Safety and Efficacy Trial of Escalation of Plerixafor for Mobilization of CD34+ Hematopoietic Progenitor Cells and Evaluation of Globin Gene Transfer in Patients With Sickle Cell Disease	25	July 2025 (active, not recruiting)

NCT04293185[a]	A Phase 3 Study Evaluating Gene Therapy by Transplantation of Autologous CD34+ Stem Cells Transduced Ex Vivo With the BB305 Lentiviral Vector in Subjects With Sickle Cell Disease	35	Nov 2027
Unpublished			
NCT02989701	Pilot and Feasibility Trial of Plerixafor for Hematopoietic Stem Cell (HSC) Mobilization in Patients With Sickle Cell Disease	6	Dec 2017

[a] Industry sponsored.
NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	C9399, J2562, J3393, J3394, J3490, J3590

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
02/01/2025	Reactivated policy. Plerixafor (Mozobil®) may be considered medically necessary for non-oncologic indications when used in combination with other therapies when ALL the following criteria are met: The individual meets criteria for approval of the primary therapy (i.e., betibeglogene autotemcel [Zynteglo®], OR lovotibeglogene autotemcel [Lyfgenia®], OR exagamglogene autotemcel [Casgevy™]; AND The prescribing information of the primary therapy (i.e., betibeglogene autotemcel [Zynteglo®], OR lovotibeglogene autotemcel [Lyfgenia®], OR exagamglogene autotemcel [Casgevy™]) indicates that plerixafor (Mozobil®) in necessary for the administration of the primary therapy. Title changed from Plerixafor

	Injection (Mozobil). Refer to RX502.061 Oncology Medications for the use of Plerixafor (Mozobil®) for oncologic indications.
4/1/2020	Document became inactive. Oncologic indications moved to RX502.061 Oncology Medications.
3/15/2020	Document updated with literature review. Coverage unchanged. Reference 2 added.
3/15/2018	Document updated with literature review. Coverage unchanged.
8/1/2016	Reviewed. No changes.
2/15/2015	Document updated with literature review. Coverage unchanged.
11/15/2012	Document updated with literature review. The following was added: Treatment using Mozobil for acute myeloid leukemia, germ cell tumors, Hodgkin's disease, acute liver failure, lung cancer, metastatic neuroblastoma, testicular cancer, thalassemia major, or WHIM (warts, hypogammaglobulinemia, infections, and myelokathexis) syndrome is considered experimental, investigational and unproven.
1/1/2010	New medical document. Plerixafor injection (Mozobil ™) may be considered medically necessary when criteria are met.