NHS England

Clinical Commissioning Policy: Use of Plerixafor for Stem Cell Mobilisation (Update)

Reference: NHS England B04/P/b

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Clinical Commissioning Policy: Use of Plerixafor for Stem Cell Mobilisation (update)

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Description	NHS England will routinely commission use of Plexifor, a drug that ensures successful stem cell collection in adults and children requiring an autologous stem cell transplant. Plerixafor can be used when usual treatment fails to secure the collection of sufficient cells. This update clarifies the criteria for use.
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Document Status

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Policy Statement

NHS England will commission plerixafor for stem cell mobilisation in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Throughout the production of this document, due regard has been given to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited in under the Equality Act 2010) and those who do not share it, has been given throughout the development of the policies and processes cited in this document.

Plain Language Summary

Currently a small number of patients requiring a stem cell transplant for myeloma or lymphoma are prevented from proceeding to treatment because it is not possible to collect enough cells. Although a second attempt to collect these cells can be tried, it requires a hospital admission and use of stronger chemotherapy. Plerixafor can be used (without chemotherapy) as an alternative in a second attempt at collecting the stem cells.

This has been shown to be highly effective and also safely administered as part of an outpatient attendance. This is termed rescue use of plerixafor. In addition, patients who appear to be heading for a failure to collect enough cells (according to agreed clinical indicators) can be given plerixafor pre-emptively, to try and prevent them from having a collection failure in the first place.

1. Introduction

Patients with Multiple Myeloma (MM), Hodgkin's Disease (HD) and Non-Hodgkin's Lymphoma (NHL) may be successfully treated with high dose chemotherapy followed by autologous transplantation of peripheral blood stem cells (PBSC). This is standard treatment for certain groups of patients with these disorders and is in accordance with local and national guidance (BSBMT Indications Table 2012).

Prior to the autologous transplant a 'mobilisation' procedure is required to increase the number of circulating PBSC in the blood compared to the resting state. These circulating PBSC can then be collected using a cell separator using a procedure called apheresis. Current mobilisation protocols combine the use of intravenous chemotherapy with administration of a growth factor called G-CSF which, when combined, results in successful mobilisation and collection of PBSC in approximately 80% of patients. About 10 -20% of the above patients fail to collect enough cells to proceed to the autologous transplant. Usually in order to proceed to the planned transplant, these patients are offered a second round of stem cell mobilisation and stem cell collection using a more intensive chemotherapy approach which requires a further inpatient admission, additional chemotherapy and G-CSF costs, and has associated toxicity (e.g. prolonged cytopenias, infections etc). Additional attempts at mobilisation are only effective in a small number of patients (up to 20%).

The recent introduction of plerixafor combined with G-CSF has been shown to increase the PBSC yield and can result in successful mobilisation of PBSC in up to 80% of patients who have previously failed to collect sufficient cells (rescue treatment). In addition, when plerixafor is administered following chemotherapy and G-CSF in patients with a low level of circulating stem cells in the blood on the predicted day of collection, it can enhance the number of stem cells mobilising into the blood and avoid a failure of PBSC harvesting (pre-emptive treatment). This then avoids the need for a second attempt at mobilisation. The use of plerixafor avoids the cost of further hospital bed days and the additional G-CSF and chemotherapy administration, avoids the toxicity and complications of the more intensive chemotherapy treatment and allows patients to move forward to their proposed transplant more quickly which can be critical in preventing disease progression prior to the planned transplant.

2. Definitions

Stem Cell Mobilisation – this means the successful increase in the number of stem cells (PBSC) circulating in the blood from where they can be collected.
Stem Cell Harvest – this means the collection of the stem cells (PBSC) from the blood using a cell separator machine.

Apheresis – this is the name given to the flow of the patient's blood through the cell separator during which the stem cells (PBSC) are separated and collected into a separate container in which they can then be frozen for later use.

CD34+ cell – this is the protein expressed on the stem cells (PBSC) that we can detect allowing us to count the number of stem cells in the blood or the harvest

product.

Target dose – optimal number of PBSC (CD34+ cells) required to safely proceed to a transplant.

Autologous stem cell transplant – this is the process of high dose chemotherapy followed by infusion of the harvested stem cells which will repopulate the bone marrow and allow the recovery of the patient's blood counts.

3. Aim and objectives

This policy aims to:

- Identify which patients are suitable for the use of plerixafor to augment stem cell mobilisation and collection.

The objectives are to:

- Reduce the number of patients failing stem cell mobilisation who have to undergo further attempts at stem cell mobilisation using more intensive chemotherapy.
- Reduce the number of patients who are unable to have the planned autologous stem cell transplant due to insufficient stem cells being collected. Currently these patients may either be ineligible for a transplant procedure which may negatively impacting on their survival, or alternatively may instead have to undergo allogeneic transplantation which is a more complex procedure with higher costs and morbidity.

4. Epidemiology and needs assessment

Approximately 10-20% of patients undergoing stem cell mobilisation fail to collect an adequate number of stem cells to proceed to stem cell transplant at the first attempt. These patients would be eligible for either rescue or pre-emptive treatment with plerixafor.

Data from Nottingham and Glasgow show that approximately 16% of patients will require pre-emptive plerixafor, of which > 90% can then successfully be mobilised following intervention with pre-emptive plerixafor, preventing the requirement for second mobilisation attempt (data not published).

5. Evidence base

Plerixafor (Mozobil, AMD3100) is a potent, selective and transient antagonist of the CXCR4 chemokine receptor and blocks binding of its cognate ligand, stromal cell–derived factor-1 (SDF-1), also known as CXCL12. It mobilises stem cells from the bone marrow increasing their number in peripheral blood. Unlike G-CSF, plerixafor is not a growth factor but works alongside G-CSF to release cells more efficiently (1-3). This drug was introduced into the UK in August 2009.

Plerixafor has been used in a variety of settings. However, this policy focuses only on the use of plerixafor in two settings: 1) after a failed prior mobilisation (rescue mobilisation), 2) for mobilisation in patients with ongoing low CD34+ cell counts to

prevent a mobilisation and collection failure (pre-emptive use).

There is RCT data to suggest that plerixafor combined with G-CSF is superior to G-CSF alone as a first mobilisation strategy, but in the UK chemotherapy plus G-CSF is the standard mobilisation regimen and in view of the cost of plerixafor, this policy is only concerned with patients who have failed or are failing stem cell mobilisation. Upfront use of plerixafor is not being considered or recommended.

Evidence for Plerixafor following Mobilisation Failure

On average, up to 20% of patients undergoing standard mobilisation attempts fail to reach the accepted minimum of 2×10^6 CD34+ cells/kg of the patient's body weight [4, 5]. The definition for difficult-to-mobilise patients varies but in general includes the following characteristics:

- peripheral blood CD34+ cell counts are low ($<10 \times 10^6$/L in many centers)
- minimal collection target ($>2 \times 10^6$ CD34+ cells/kg) is not achieved with a single mobilisation

Remobilisation is a viable option in patients who have failed mobilisation with the first attempt or in whom a suboptimal graft has been collected. Historically, chemotherapy-based remobilisation has been often advocated in patients who have failed a first mobilisation (6). In a recent single-centre series using predominantly G-CSF for mobilisation (>90% of cases), the success rate of a remobilisation was only 23% as a whole (3). Failure rates were 73.5% in patients remobilised with chemotherapy plus G-CSF, 81.6% in patients remobilised with growth factor alone but only 27.8% in patients mobilised with G-CSF plus plerixafor.

Plerixafor combined with G-CSF has significantly increased the efficacy of remobilisation in patients who have failed a previous mobilisation attempt with a success rate of greater than 60% (5). In a compassionate-use study of 115 patients who had failed a previous mobilisation, the success rate ($>2 \times 10^6$/kg $CD34^+$ cells collected) of G-CSF plus plerixafor was 60.3% for NHL, 71.4% for MM and 76.5% for HL, respectively (6). Similarly, in an EU compassionate-use series, combination of G-CSF and plerixafor gave successful collections in 75% of patients who had failed a previous mobilisation (12).

Most of these patients achieved a timely and stable engraftment with rare and/or manageable side effects (4,7,10).

Evidence for Pre-Emptive Plerixafor

The use of plerixafor in conjunction with chemotherapy and G-CSF to salvage a mobilisation failure is now being increasingly used. Existing published results indicate that the combination is safe and effective. Peripheral blood CD34+ cell counts are increased several-fold in more than 90% of patients to allow collection of the target yield (4, 10). In one study, patients failing mobilisation with chemotherapy

plus G-CSF achieved a 2.7-fold increase in median hematopoietic progenitor cell (HPC) product concentration after plerixafor was added.

A further study showed PBSC collection data of 38 consecutive patients with lymphoma (Hodgkin's and non-Hodgkin's) and MM who underwent chemo-mobilisation and high-dose G-CSF and just-in-time plerixafor in order to evaluate the efficacy of this treatment combination. All patients with MM and all but one patient with lymphoma (95% of total patients) collected the minimum required number of CD34+ cells to proceed with autologous stem cell transplantation (>2 × 10^6/kilogram of body weight) (13).

Cost-Effectiveness

Plerixafor is a high cost drug, costing £4883 per vial plus VAT.

Cost analyses have been performed by multiple groups and some studies have claimed a cost saving by using plerixafor (7, 8), while other studies have shown an increase in cost that may be justified by fewer apheresis sessions and a greater likelihood of collecting enough stem cells to proceed to transplantation(7).

The Scottish Medicines Consortium reviewed and approved plerixafor for use in NHS Scotland within its licensed indications (14). The manufacturer presented a cost-utility analysis of the use of plerixafor for mobilisation in MM and NHL patients who had failed at least one previous mobilisation attempt. The comparator mobilisation treatments were G-CSF and GCSF in combination with cyclophosphamide.

Rates of successful mobilisation were drawn from a range of sources, data from the compassionate use programme being used for plerixafor while a retrospective analysis was used for G-CSF and G-CSF + cyclophosphamide. Successful mobilisation was followed by autologous transplantation, while those not mobilising were largely assumed to undergo chemotherapy. The effectiveness, survival estimates and utility estimates for these were taken from the literature. Adverse events during mobilisation were not considered.

The key results in MM patients were as follows:

- The cost per successful mobilisation gained was £12,768 compared to G-CSF
- The cost per successful mobilisation gained was £11,074 compared to G-CSF + cyclophosphamide
- A gain of 0.47 quality-adjusted life year (QALY) is at a cost of £18,832 compared to G-CSF, to yield a cost per QALY of £39,649
- A gain of 0.41 QALYs at a cost of £15,561compared to G-CSF + cyclophosphamide, to yield a cost per QALY of £38,278.

The key results in NHL patients were as follows:

- The cost per successful mobilisation gained was the same as among multiple myeloma patients

- A gain of 1.22 QALYs at a cost of £23,950 compared to G-CSF, to yield a cost per QALY of £19,586
- A gain of 1.06 QALYs at a cost of £20,054 compared to G-CSF + cyclophosphamide, to yield a cost per QALY of £18,874 compared to G-CSF + cyclophosphamide.

Most cost-effectiveness studies have not fully captured the variables needed to justify its use, including the cost of delayed transplant which would include

- additional cycles of chemotherapy including inpatient bed days
- increased risk of relapse
- neutropenic fevers requiring further treatment.

In June 2010, the London Cancer New Drugs Group (15) estimated that treating a patient with plerixafor cost £10 - £20K per patient. They calculated the additional cost for the drug per 100,000 population to be £8906 (excluding VAT), although clinical opinion suggests that lower dosing may reduce this cost further.

Post transplant costs may be different when plerixafor is used and these costs have not yet been estimated. For example, plerixafor may mobilise more lymphocytes and lymphocyte precursors in the product, which may result in better outcomes.

A study by Shaughnessy and colleagues (9) suggests that the cost of remobilisation with plerixafor and GCSF and chemo mobilisation (intensive chemotherapy and GCSF) are similar once the cost of hospitalisation is considered.

The average number of bed days saved for a further course of mobilising chemotherapy would be 5 days. In addition another advantage of plerixafor is that the toxicity of chemotherapy can often be avoided such as reduced admissions with neutropenic sepsis (currently over 20% of patients receiving chemo-mobilisation) and the need for blood products. The use of plerixafor pre-emptively to avoid mobilisation failure also reduces the cost of bed days required for another cycle of mobilising chemotherapy and further GCSF costs.

Plerixafor has been shown to cause less mobilisation and collection failures and can mobilise patients who have failed a prior mobilisation attempt, allowing more patients to proceed to transplantation, improving the patient experience. Furthermore the collection of PBSC following plerixafor is highly predictable making it highly convenient for patients and collection centres alike.

Prior to the instigation of national commissioning plerixafor was in use in many transplant centres throughout England, either through prior approval for specified indications or via Individual Funding Requests (IFRs). The aim of this policy is to make access to the drug equitable across the country for the specific groups of patients indicated.

In summary, in patients failing mobilisation, further attempts at mobilisation increase the cost of the procedure whatever option is used. The cost of use of plerixafor can be considered against other options of high intensity chemotherapy or allograft transplant. The proportion of patients failing mobilisation is constant at up to 20%

and the number of patients affected is unchanged whether rescue or pre-emptive use is considered. The greater success of plerixafor in achieving sufficient mobilisation means that more eligible patients will be able to proceed to transplant.

Safety

Plerixafor is well tolerated with few adverse events. Common adverse effects include diarrhea, injection site erythema, perioral numbness, sinus tachycardia, headache, nausea, abdominal distention, and injection site pain. It does not cause neutropenia or other cytopenias.

6. Rationale behind the policy statement

There is a clinical need for some patients to undergo an additional mobilisation attempt following a failure of initial mobilisation in order to proceed to planned transplant. Plerixafor is safe and effective drug for enhancing stem cell mobilisation with very little toxicity.
The recommendation for the use of plerixafor for such remobilisation attempts following a failed mobilisation is based on Grade B1 evidence.

There is emerging data that patients with low CD34+ cell counts on the day of planned harvesting can avoid a failed mobilisation attempt by the pre-emptive administration of plerixafor on that day. This reduces the need for remobilisation and allows transplantation to proceed on schedule, with the additional benefits in terms of disease control. Using plerixafor at this earlier time point does not increase the number of patients requiring plerixafor, but uses it more efficiently by adding it to the first attempt rather than using it during a second mobilisation attempt

The recommendation for the use of plerixafor pre-emptively for patients meeting the criteria outlined indicating poor mobilisation is based on Grade C1 evidence. There is likely to be increasing evidence available regarding its use in this area which would need to be regularly reviewed.

7. Criteria for commissioning

Patient selection

Patients eligible for treatment with plerixafor are Hodgkin's Disease (HD) Non-Hodgkin's lymphoma (NHL) or multiple myeloma (MM) patients who meet the standard criteria and are scheduled for an autologous haematopoietic stem cell transplant but:

1) have failed one previous attempt at mobilisation using a standard mobilisation regimen combining chemotherapy + G-CSF or G-CSF alone (rescue treatment). These patients will be offered a second mobilisation attempt with planned use of combination high dose G-CSF and plerixafor

   or

2) while undergoing mobilisation with a standard chemotherapy + G-CSF or G-CSF based regimen, have a low peripheral blood CD34+ cell count on the day of expected harvest and are not considered by the transplant consultant

to have a reasonable chance of collecting enough cells (pre-emptive treatment). These patients will be given plerixafor as an unplanned addition to their mobilisation regimen.

Starting and Stopping Criteria

1) Patients who have previously failed a mobilisation attempt (rescue) should receive G-CSF (10 µg/kg, or in accordance with protocol) subcutaneously each day for 4 consecutive days. (It is usually prescribed to the nearest ampoule size multiple, in accordance with transplant centre policy):

- On the fourth day patients assessed as requiring plerixafor (usually if the peripheral blood CD34+ cell number are < 15 per microlitre) receive a dose of 240 µg/kg in the early evening as a subcutaneous injection into the abdomen.
- On the morning of the fifth day, a full blood count and peripheral CD34 count should be performed prior to harvest. It is the responsibility of the Transplant Consultant, to decide whether the harvest should proceed on the basis of the blood CD34+ estimation (usually if above 10 CD34+ cells per microlitre).
- If the count is insufficient to harvest cells that day, or if insufficient stem cells have been harvested, then patients should receive a further dose of GCSF and a repeat dose of plerixafor (240 µg/kg) that evening in an identical fashion to the day before. A second attempt at harvest should be made the following day.

2) Patients who appear to be failing a mobilisation attempt (pre-emptive) – these are patients in whom the CD34+ cell count in the blood is < 15 per microlitre on the day of predicted day of stem cell harvest.

- These patients are given a dose of subcutaneous plerixafor with GCSF 10 µg/kg and an attempt at harvesting is made the following day if the repeat CD34+ is sufficient.
- If the CD34 level in the blood remains < 15 per microlitre then the harvest should be delayed and a further dose of G-CSF and plerixafor may be given that evening.

Stopping Criteria

- A maximum of three doses of plerixafor in total may be used.
- In general a collection totalling >2 X (106) CD34+ cells per kilogram body weight will be sufficient to adequately support a single high-dose therapy procedure.

Exclusions

- Plerixafor should not be used in pregnant patients, and male and female patients should be recommended to use suitable birth control for three months during and after its use.
- Plerixafor is not funded for patients undergoing a first attempt at stem cell mobilisation unless they meet the criteria for pre-emptive therapy.
- Plerixafor should not be used for patients who have already received it pre-emptively during a previous attempt at mobilsation.

8. Patient pathway

Patients for stem cell harvesting will normally be referred to the stem cell collection unit by the transplant team with a written prescription detailing the target stem cell dose required as per JACIE and Human Tissue Authority (HTA) recommendations. Either the transplant team or the collection team (depending on local factors) will be responsible for the authorisation and administration of plerixafor for patients requiring this intervention. There will be no change to existing arrangements following approval of this policy.

9. Governance arrangements

- Consent, patient evaluation and investigations prior to the commencement of the mobilisation procedure must be carried out at the stem cell collection centre in accordance with relevant transplant centre policy.
- No additional investigations are required for the provision of plerixafor.
- All processes involved in the provision of plerixafor and the subsequent harvesting of peripheral blood stem cells must fulfill Human Tissue Authority (HTA) requirements and must meet JACIE accreditation standards.

10. Mechanism for funding

From April 2013 NHS England is the responsible commissioner for stem cell transplant. Monitoring of the use of plerixafor in accordance with this policy will be expected in the form of audit data.

11. Audit requirements

Regular audit should be carried out on the use of plerixafor. Audit criteria will encompass the following:

- % of total patients undergoing mobilisation who require plerixafor
- Number of doses of plerixafor used per patient
- Total CD34+ cells mobilised or sufficient CFU (colony forming units) following plerixafor
- Number of collection days required to obtain sufficient cells for indicated PBSCT
- Time to neutrophil and platelet engraftment following PBSCT to assess the quality of the stem cell harvested.

12. Documents which have informed this policy

Not applicable

13. Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

14. Date of review

This policy will be reviewed in April 2016 unless information is received which indicates that the proposed review date should be brought forward or delayed.

References

1. Uy, GL *et al.* Plerixafor, a CXCR4 antagonist for the mobilisation of haematopoietic stem cells Expert Opin. Biol. Ther. (2008) 8(11):1797-1804

2. Pusic, I et al. Impact of mobilisation and remobilisation strategies on achieving sufficient stem cell yields for autologous transplantation. Biology of Blood and Marrow Transplantation. 2008, 14: 1045-1056.

3. Rosenkilde MM, Gerlach LO, Jakobsen JS, Skerlj RT, Bridger GJ, Schwartz TW. Molecular mechanism of AMD3100 antagonism in the CXCR4 receptor: transfer of binding site to the CXCR3 receptor. J Biol Chem. 2004; 279:3033-3041.

4. *Hubel K, Fresen MM, Salwender H, Basara N, Beier R, Theurich S, Christopeit M, Bogner C, Galm O, Hartwig R, Heits F, Lordick F, Rosler W, Wehler D, Zander AR, Albert MH, Dressler S, Ebinger M, Frickhofen N, Hertenstein B, Kiehl M, Liebler S, von Lilienfeld-Toal M, Weidmann E, Weigelt C, Lange F, Kroger N.* Plerixafor with and without chemotherapy in poor mobilisers: results from the German compassionate use program*. Bone Marrow Transplant 2011;46:1045-1052*

5. *Jantunen E, Kvalheim G.* Mobilisation strategies in hard-to-mobilise patients with lymphoid malignancies*. Eur J Haematol 2010;85:463-471.*

6. Calandra G, McCarty J, McGuirk J, Tricot G, Crocker SA, Badel K, Grove B, Dye A, Bridger G. AMD3100 plus G-CSF can successfully mobilise $CD34^+$ cells from non-Hodgkin's lymphoma, Hodgkin's disease and multiple myeloma patients previously failing mobilisation with chemotherapy and/or cytokine treatment: compassionate use data*. Bone Marrow Transplant 2008;41:331–8.*

7. Arcaini L, Laszlo D, Rizzi S, Balzarotti M, Antoniazzi F, Zilioli VR, Guggiari E, Farina L, Todisco E, Bonfichi M, Alamos SM, Rossi G, Martinelli G, Morra E. Plerixafor and G-CSF for PBSC mobilisation in patients with lymphoma who failed previous attempts with G-CSF and chemotherapy: a REL (Rete Ematologica Lombarda) experience*. Leuk Res 2011;35:712-714.*

8. *Vishnu P, Roy V, Paulsen A, Zubair AC.* Efficacy and cost-benefit analysis of risk-adaptive use of plerixafor for autologous hematopoietic progenitor cell mobilisation*. Transfusion 2011;52:55-62*

9. *Shaughnessy P, Islas-Ohlmayer M, Murphy J, Hougham M, MacPherson J, Winkler K, Silva M, Steinberg M, Matous J, Selvey S, Maris M, McSweeney PA.* Cost and clinical analysis of autologous hematopoietic stem cell mobilisation with G-CSF and plerixafor compared to G-CSF and cyclophosphamide*. Biol Blood Marrow Transplant 2011;17:729-736*

10. Calandra, G *et al*. AMD3100 plus G-CSF can successfully mobilise CD34+ cells from non-Hodgkin's lymphoma, Hodgkin's disease and multiple Myeloma patients previously failing mobilisation with chemotherapy and/or cytokine treatment: compassionate use data. *Bone Marrow Transplantation* (2008) 41: 331–338

11.*D'Addio A, Curti A, Worel N, Douglas K, Motta MR, Rizzi S, Dan E, Taioli S, Giudice V, Agis H, Kopetzky G, Soutar R, Casadei B, Baccarani M, Lemoli RM.* The addition of plerixafor is safe and allows adequate PBSC collection in multiple myeloma and lymphoma patients poor mobilisers after chemotherapy and G-CSF*. Bone Marrow Transplant 2011;46:356-363*

12. *Duarte RF, Shaw BE, Marin P, et al.* Plerixafor plus granulocyte CSF can mobilise hematopoietic stem cells from multiple myeloma and lymphoma patients failing previous mobilisation attempts: EU compassionate use data*. Bone Marrow Transplant 2010; March 22*

13 Smith VR, Popat U, Ciurea S, Nieto Y, Anderlini P, Rondon G, Alousi A, Qazilbash M, Kebriaei P, Khouri I, de Lima M, Champlin R, Hosing C. Just-in-time rescue plerixafor in combination with chemotherapy and granulocyte-colony stimulating factor for peripheral blood progenitor cell mobilisation. *Am J Hematol.* 2013 Jun 8. doi: 10.1002/ajh.23499. [Epub ahead of print]

14 NHS Scotland, Scottish Medicines consortium - plerixafor, 20mg/ml solution for injection (Mozobil) No. (594/09) Genzyme Therapeutics Limited, 04 December 200904 December 2009

15 London Cancer New Drugs Group, APC/DTC Briefing - Plerixafor for Stem Cell mobilisation prior to BMT, June 2010
http://www.medicinesresources.nhs.uk/upload/documents/Evidence/Drug%20Specific%20Reviews/Plerixafor_for_Stem_Cell_mobilisation_prior_to_BMT.pdf

Change Notice for

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Amendment **to the Published Products**

Product Name	**Clinical Commissioning Policy: Use of Plerixafor for Stem Cell Mobilisation (Update)**
Ref No	**NHS ENGLAND B04/P/b**
CRG Lead	**BMT CRG – Claire Foreman**

Description of changes required

Describe what was stated in original document	Describe new text in the document	Section/Paragraph to which changes apply	Describe why document change required	Changes made by	Date change made
Commissioning criteria stated that the following regimen was required before Plerixafor could be used have failed one previous attempt at mobilisation using a standard	Replaced with have failed one previous attempt at mobilisation using a standard	Section 7 – Criteria for commissioning Sub heading : Patient selection Paras 3 & 4	In clinical practice, mobilisation regimens used include chemo+G-CSF or G-CSF alone. The correction clarifies patients mobilised with G-CSF who are failing to mobilise are not excluded from access to plerixafor.	Approved by CRG Chair Changes made by Accountable Commissioner	June 2014

mobilisation regimen combining chemotherapy and G-CSF alone (rescue treatment). … or while undergoing mobilisation with a standard chemotherapy and G-CSF based regimen, ….	mobilisation regimen combining chemotherapy + G-CSF or G-CSF alone (rescue treatment)…. or while undergoing mobilisation with a standard chemotherapy + G-CSF or G-CSF based regimen, …..				
Reference was B04/P/2	Consistent with naming convention change to B04/P/b	Title	Inconsistent naming convention	Approved by CRG Chair Changes made by Accountable Commissioner	June 2014