

<u>Field Name</u>	<u>Field Description</u>
<u>Prior Authorization Group Description</u>	<u>Omisirge</u>
<u>Drugs</u>	<u>Omisirge (omidubicel-only)</u>
<u>Covered Uses</u>	<u>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</u>
<u>Exclusion Criteria</u>	<u>Patient has previously received this medication</u>
<u>Required Medical Information</u>	<u>See “Other Criteria”</u>
<u>Age Restrictions</u>	<u>According to package insert</u>
<u>Prescriber Restrictions</u>	<u>Prescribed by or in consultation with an oncologist</u>
<u>Coverage Duration</u>	<u>If all the criteria are met, the initial request will be approved for a one-time treatment.</u>
<u>Other Criteria</u>	<p><u>**Drug is being requested through the member’s medical benefit**</u></p> <p><u>Initial Authorization:</u></p> <ul style="list-style-type: none"> <u>• Patient has a hematologic malignancy planned for umbilical cord blood transplantation (UCBT) following myeloablative conditioning</u> <u>• Prescriber attests that the patient is eligible for myeloablative allogeneic hematopoietic stem cell transplantation (HSCT) AND does not have a readily available matched related donor, matched unrelated donor, mismatched unrelated donor, or haploidentical donor</u> <u>• Patient has not received a prior allogeneic HSCT</u> <u>• Patient does not have known allergy to dimethyl sulfoxide (DMSO), Dextran 40, gentamicin, human serum albumin, or bovine material</u> <p><u>The safety and effectiveness of repeat administration of Omisirge have not been evaluated and will not be approved.</u></p> <p><u>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</u></p>
<u>Review/Revision Date: 7/2024</u>	