Chemotherapy: Multiple Myeloma Drugs

Zolgensma (onasemnogene) J3399, Darzalex (daratumumab) J9145, Empliciti (elotuzumab) J9176, Kyprolis (carfilzomib) J9047, Sarclisa (isatuximab-irfc) J9227, Elrexfio (elranatamab-bcmm) J1323, Talvey (talquetamab-tgvs) J3055, Tecvayli (teclistamab-cqyv) C9148, Abecma (idecabtagene vicieucel) Q2055, Carvykti (ciltacabtagene autoleucel) Q2056

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**NEW START - Start Date:**_____	☐ **Continuation** (within 365 days)**:** Date of last treatment _____
☐	Date Requested _____	
	Requestor _____ Clinic name: _____ Phone / Fax	

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug ☐ Self-administered	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ New Start or Initial Request: (Clinical documentation required for all requests)

☐ **Elrexfio** (**J1323**) -- Patient has tried and failed at least four prior therapies including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 Antibody II

☐ **Tecvayli** (**C9148**) -- Patient has tried and failed at least four prior therapies including a proteasome inhibitor, an immunomodulatory drug, and an anti-CD38 Antibody II

☐ **Talvey** (**J3055**) --

- ☐ Patient with relapsed or refractory multiple myeloma after at least 4 prior lines of therapy
- ☐ Patients must have been treated with all of the following:
  - ☐ An immunomodulatory agent
  - ☐ A proteasome inhibitor
  - ☐ An anti-CD38 antibody

☐ Must have active disease defined by at least one of the following:
- ☐ Serum M-protein greater or equal to 1.0 g/dL
- ☐ iUrine M-protein greater or equal to 200 mg/24h
- ☐ Serum free light chain (FLC) assay greater or equal to 10 mg/dL provided the baseline serum
- ☐ FLC ratio is abnormal

☐ Patients must meet all of the following
- ☐ ECOG performance status of 0 - 2
- ☐ No known central nervous system involvement with myeloma
- ☐ Alanine aminotransferase (ALT) and aspartate aminotransferase (AST) less than or equal to 3 times the upper limit of normal (ULN)
- ☐ Creatinine clearance greater than or equal to 40 mL/min
- ☐ No detectable hepatitis B or C viral load
- ☐ No infection that is uncontrolled or requires IV or long-term oral antimicrobial therapy
- ☐ Left ventricular ejection fraction greater than or equal to 40%
- ☐ No stroke event within 6 months of therapy administration
- ☐ No pulmonary disease requiring oxygen dependence
- ☐ No seizures within 6 months of therapy administration
- ☐ No active autoimmune disease except vitiligo, type 1 diabetes mellitus, or prior autoimmune thyroiditis

☐ Have not received prior treatment with any CD3-GRPC directed T-cell engager
- ☐ Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: Multiple Myeloma PA

Drug Name(s):

DARZALEX	**ZOLGENSMA**
EMPLICITI	**ABECMA**
KYPROLIS	**SARCLISA**
CARVYKTI	**ELREXFIO**
TALVEY	**TECVAYLI**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Approval will be for 12 months
Zolgensma: To be individually determined

FDA Indications:

Darzalex

- Multiple myeloma, In combination with pomalidomide plus dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- Multiple myeloma, Relapsed or refractory, in combination with lenalidomide and dexamethasone in patients who have received at least one prior therapy
- Multiple myeloma, Monotherapy, in patients who have received at least 3 prior therapies including a proteasome inhibitor and an immunomodulatory agent or are double-refractory to a proteasome inhibitor and an immunomodulatory agent
- Multiple myeloma, In combination with bortezomib, melphalan, and predniSONE in newly diagnosed patients who are ineligible for autologous stem cell transplant
- Multiple myeloma, In combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant
- Multiple myeloma, In combination with bortezomib plus dexamethasone in patients who have received at least one prior therapy
- Multiple myeloma, Newly-diagnosed, in combination with lenalidomide and dexamethasone in patients who are ineligible for autologous stem cell transplant

- Multiple myeloma, Relapsed or refractory, in combination with carfilzomib plus dexamethasone, after 1 to 3 prior therapies

Elrexfio, Talvey, Tecvayli
- Multiple myeloma, Relapsed or refractory, in patients who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody

Empliciti
- Multiple myeloma, In combination with lenalidomide and dexamethasone following treatment with 1 to 3 prior therapies
- Multiple myeloma, In combination with pomalidomide and dexamethasone following treatment with at least 2 prior therapies including lenalidomide and a proteasome inhibitor

Kyprolis
- Multiple myeloma, Relapsed or refractory, in combination with daratumumab plus dexamethasone, after 1 to 3 prior therapies
- Multiple myeloma, Relapsed or refractory, in combination with daratumumab plus dexamethasone or daratumumab/hyaluronidase-fihj plus dexamethasone, after 1 to 3 prior therapies
- Multiple myeloma, Relapsed or refractory, in combination with isatuximab plus dexamethasone, after 1 to 3 prior therapies
- Multiple myeloma, Relapsed or refractory, monotherapy, after at least 1 prior therapy

Abecma, Carvykti
- Multiple myeloma, Relapsed or refractory, after 4 or more prior lines of therapy

Sarclisa
- Multiple myeloma, In combination with pomalidomide and dexamethasone in patients who have received at least two prior therapies including lenalidomide and a proteasome inhibitor
- Multiple myeloma, Relapsed or refractory, in combination with carfilzomib and dexamethasone in patients who have received 1 to 3 prior lines of therapy

Zolgensma
- Spinal muscular atrophy, Bi-allelic survival motor neuron 1 (SMN1) gene mutations

Off-Label Uses:

Darzalex
- AL amyloidosis, Relapsed or refractory

Kyprolis
- Multiple myeloma, Newly diagnosed, transplant-eligible, in combination with lenalidomide, bortezomib, and dexamethasone

Kyprolis
- Multiple myeloma, Newly diagnosed, transplant-eligible, in combination with an immunomodulatory drug and steroid
- Multiple myeloma, Newly diagnosed, transplant-ineligible, in combination with a chemotherapy agent and a steroid
- Waldenstrom macroglobulinemia

Age Restrictions:

Safety and effectiveness not established in pediatric patients

Other Clinical Considerations:

Carvykti:

- Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients following treatment with ciltacabtagene autoleucel. Do not administer ciltacabtagene autoleucel to patients with active infection or inflammatory disorders. Treat severe or life-threatening CRS with tocilizumab or tocilizumab and corticosteroids.
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), which may be fatal or life-threatening, occurred following treatment with ciltacabtagene autoleucel, including before CRS onset, concurrently with CRS, after CRS resolution, or in the absence of CRS. Monitor for neurologic events after treatment with ciltacabtagene autoleucel. Provide supportive care and/or corticosteroids as needed.
- Parkinsonism and Guillain-Barré syndrome and their associated complications resulting in fatal or life-threatening reactions have occurred following treatment with ciltacabtagene autoleuce.
- Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS), including fatal and life-threatening reactions, occurred in patients following treatment with ciltacabtagene autoleucel. HLH/MAS can occur with CRS or neurologic toxicities.
- Prolonged and/or recurrent cytopenias with bleeding and infection and requirement for stem cell transplantation for hematopoietic recovery occurred following treatment with ciltacabtagene autoleucel.
- Ciltacabtagene autoleucel is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the ciltacabtagene autoleucel REMS Program

Elrexfio, Talvey, Tecvayli

- **Black Box Warning:** Warning: Cytokine Release Syndrome and Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome
- Cytokine Release Syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving elranatamab-bcmm. Initiate treatment with elranatamab-bcmm step-up dosing schedule to reduce the risk of CRS. Withhold elranatamab-bcmm until CRS resolves or permanently discontinue based on severity.
- Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and serious and life-threatening reactions, can occur in patients receiving elranatamab-bcmm. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment. Withhold elranatamab-bcmm until the neurologic toxicity resolves or permanently discontinue based on severity.
- **Elrexfio** - Because of the risk of CRS and neurologic toxicity, including ICANS, elranatamab-bcmm is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called **ELREXFIO REMS**
- **Talvey/Tecvayli** - Because of the risk of CRS and neurologic toxicity, including ICANS, talquetamab-tgvs is available only through a restricted program called the **TECVAYLI and TALVEY Risk Evaluation and Mitigation Strategy (REMS)**

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/015132/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/B7B02D/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931659&contentSetId=100&title=Daratumumab&servicesTitle=Daratumumab&brandName=Darzalex&UserMdxSearchTerm=Darzalex&=null#

https://www.micromedexsolutions.com/micromedex2/librarian/CS/8CBBE1/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/9FE564/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=931664&contentSetId=100&title=Elotuzumab&servicesTitle=Elotuzumab&brandName=Empliciti&UserMdxSearchTerm=Empliciti&=null#

https://www.micromedexsolutions.com/micromedex2/librarian/CS/069A6D/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/225248/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=930254&contentSetId=100&title=Carfilzomib&servicesTitle=Carfilzomib&brandName=Kyprolis&UserMdxSearchTerm=Kyprolis&=null#

https://www.micromedexsolutions.com/micromedex2/librarian/CS/D8EF8E/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/566E37/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932866&contentSetId=100&title=Isatuximab-irfc&servicesTitle=Isatuximab-irfc&brandName=Sarclisa&UserMdxSearchTerm=Sarclisa&=null#

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=topHome&isToolPage=true#

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?navitem=headerLogout#