ATRIO HEALTH PLANS

Tecelra
(Afamitresgene Autoleucel) Q2057
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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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)

☐ Relapsed or Refractory Multiple Myeloma
- ☐ Patient is 18 years or older
- ☐ Confirmed diagnosis of multiple myeloma
- ☐ Patient has received at least four prior lines of therapy including:
  - ☐ Proteasome inhibitor
  - ☐ Immunomodulatory agent
  - ☐ Anti-CD38 monoclonal antibody
- ☐ Patient has relapsed or refractory disease following most recent therapy
- ☐ ECOG performance status 0-1
- ☐ Adequate organ function per prescribing information
- ☐ No active CNS involvement
- ☐ Prescribed by certified treatment center with REMS program enrollment
- ☐ Patient is not a candidate for or has failed BCMA-directed therapy

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.
☐ Medical record documentation of positive response is included

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 – Tecelra Prior Authorization

Drug Name(s):

TECELRA **AFAMITRESGENE AUTOLEUCEL**

Criteria for approval of Non-Formulary/Preferred 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 NCCN, 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, in accordance with the Label.

Exclusion Criteria:

N/A

Prescriber Restrictions:

Oncologist or other related specialist

Coverage Duration:

Approval will be for 6 months

FDA Indications:

Tecelra

- Synovial sarcoma, Unresectable or metastatic, in patients who have received prior chemotherapy, HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive, and MAGE-A4 antigen-positive

Off-Label Uses:

N/A

Age Restrictions:

Safety and effectiveness not established in pediatric patients

Other Clinical Consideration:

- Cytokine Release Syndrome (CRS), which may be severe or life-threatening, occurred in patients receiving afamitresgene autoleucel. At the first sign of CRS, immediately evaluate patient for hospitalization and institute treatment with supportive care. Ensure that healthcare providers administering afamitresgene autoleucel have immediate access to medications and resuscitative equipment to manage CRS

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidencexpert.DoIntegratedSearch?SearchTerm=Tecelra&SearchFilter=filterNone#