Clinical Oversight Review Board (CORB) Criteria for Prescribing

Brexucabtagene autoleucel (Tecartus)

Non-Formulary **brexucabtagene autoleucel (Tecartus)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **brexucabtagene autoleucel (Tecartus)** will be covered on the prescription drug benefit when the following criteria are met:

- Diagnosed with histologically confirmed relapsed or refractory mantle cell lymphoma
- Patient is at least 18 years of age
- Less than partial response to adequate trials of at least two lines of standard therapy from the following options:
  - anthracycline- or bendamustine-containing chemotherapy
  - anti-CD20 monoclonal antibody
  - Bruton's tyrosine kinase inhibitor (e.g., ibrutinib, acalabrutinib, or zanubrutinib)
  - refractory post-autologous hematopoietic stem cell transplantation (HSCT)
- At least one measurable lesion (or documented progression following completion of lesion irradiation)
  - If the only measurable disease is lymph node disease, at least one lymph node ≥2 cm
- No evidence of central nervous system lymphoma on magnetic resonance imaging (MRI)
- Eastern Cooperative Oncology Group (ECOG) performance status of ≤2
- Absolute neutrophil count ≥500/µL
- Platelet count ≥50,000/µL
- Adequate organ function defined as:
  - Left Ventricular Ejection Fraction ≥45%
  - Creatinine clearance ≥40 mL/min
  - Alanine aminotransferase (ALT) ≤5 times the upper limit of normal for age
  - Total bilirubin <2 mg/dL
  - Baseline oxygen saturation >91% on room air
- No active HIV infection or active hepatitis B or C infection
- Prior to external treatment referral for CAR-T therapy, patients should be reviewed by an Interregional Consultative Physician Panel.