Gold Coast Health Plan (GCHP) Medi-Cal Clinical Guidelines
Retifanlimab-dlwr (ZynyzTM)

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Programmed death receptor-1 (PD-1)–blocking antibody indicated: Squamous Cell Carcinoma of the Anal Canal (SCAC) • In combination with carboplatin and paclitaxel for the first-line treatment of adult patients with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC). • As a single agent for the treatment of adult patients with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy. Merkel Cell Carcinoma (MCC) for the treatment of adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC).
Exclusion Criteria	• Active bacterial, fungal, or viral infections, including hepatitis A, B, and C. • Clinically significant pulmonary, cardiac, gastrointestinal or autoimmune disorders. Pregnancy or breastfeeding.
Required Medical Information	<u>Initial – Must meet ALL of the following:</u> • Diagnosis of Merkel Cell Carcinoma (MCC) with metastatic disease or recurrent, advanced locoregional disease not amenable to surgery or radiation. • Not received systemic therapy for MCC, including chemotherapy and prior PD-1 or PD-L1-directed therapy (for example, avelumab, pembrolizumab, atezolizumab, cemiplimab, dostarlimab, durvalumab, nivolumab, etc.). • Baseline liver enzymes, creatinine, and thyroid function. <u>Renewal:</u> • Continues to meet initial approval criteria. • Positive clinical response such as stabilization of disease or decrease in tumor size or spread. Absence of disease progression or unacceptable toxicity such as immune-mediated adverse reactions, infusion-related reactions, complications of Allogeneic hematopoietic stem-cell transplantation (HSCT), etc.
Age Restriction	18 years of age and older. 18 to 21 years of age – check CCS eligibility
Prescriber Restrictions	Oncologist or hematologist
Coverage Duration	Initial – 6 months; Renewal – 12 months
Other Criteria/Information	Criteria adapted from DHCS May 2024 **HCPCS** | **Description** | **Dosing, Units**

	J9345	Injection, retifanlimab-dlwr, 1 mg (Zynyz) 500mg/20ml single dose vial	500mg IV infusion every 4 weeks	

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	Jan. 15, 2026	N/A	Yoonhee Kim, Senior Clinical Pharmacist	N/A