LUMOXITI
(moxetumomab pasudotox-tdfk)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin. Lumoxiti binds CD22 on the cell surface of B-cells and is internalized. Lumoxiti internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death (1).

Regulatory Status
FDA-approved indication: Lumoxiti is a CD22-directed cytotoxin indicated for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who received at least two prior systemic therapies, including treatment with a purine nucleoside analog (PNA) (1).

Lumoxiti has a boxed warning regarding Capillary Leak Syndrome (CLS), including life-threatening cases. CLS is characterized by hypoalbuminemia, hypotension, symptoms of fluid overload, and hemoconcentration. Patient weight and blood pressure should be monitored prior to each Lumoxiti infusion and as clinically indicated during treatment. Patients who develop CLS should receive appropriate supportive measures, including concomitant oral or intravenous corticosteroids, and hospitalization as clinically indicated. Lumoxiti should be withheld for Grade 2 CLS until resolution, and permanently discontinued for Grade ≥ 3 CLS (1).

Lumoxiti also has a boxed warning that Hemolytic Uremic Syndrome (HUS) may occur, including life-threatening cases. HUS is characterized by the triad of microangiopathic hemolytic anemia, thrombocytopenia, and progressive renal failure. Prophylactic intravenous fluids should be administered before and after Lumoxiti infusions. Blood chemistries and blood counts should be done prior to each dose and on day 8 of each treatment cycle, as well as mid-cycle. Lumoxiti should be discontinued in patients with HUS (1).

Renal toxicity can occur with Lumoxiti therapy. Renal function should be monitored prior to each infusion of Lumoxiti, and as clinically indicated throughout treatment (1).

The safety and effectiveness of Lumoxiti in pediatric patients have not been established (1).
Summary
Lumoxiti (moxetumomab pasudotox-tdfk) is a CD22-directed cytotoxin. Lumoxiti binds CD22 on the cell surface of B-cells and is internalized. Lumoxiti internalization results in ADP-ribosylation of elongation factor 2, inhibition of protein synthesis, and apoptotic cell death. The safety and effectiveness of Lumoxiti in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Lumoxiti while maintaining optimal therapeutic outcomes.

References