Clinical Management of Infusion-Related Reactions

For additional information on management of bintrafusp alfa-associated AEs, click for:

Skin AEs | irAEs | Anemia | Bleeding

NCI-CTCAE v5.0 – Grade	Recommendations for treatment modification of bintrafusp alfa for symptoms of IRRs
Grade 1: mild • Mild transient reaction; infusion interruption not indicated; intervention not indicated	• Increase monitoring of vital signs as medically indicated as patients are deemed medically stable by the attending physician
Grade 2: moderate • Therapy or infusion interruption indicated but if responds promptly to symptomatic treatment (eg, antihistamines, NSAIDs, narcotics, IV fluids); prophylactic medications indicated for ≤24 hours	• Stop infusion of the treatment causing IRR • Increase monitoring of vital signs as medically indicated as patients are deemed medically stable by the attending physician • If symptoms resolve quickly, resume infusion at 50% of original rate with close monitoring of any worsening signs and symptoms; otherwise dosing held until resolution of symptoms with mandated premedication for the next scheduled visit • If the patient has a second IRR grade ≥2 on the slower infusion rate despite premedication, the infusion should be stopped, and the attending physician may consider permanent discontinuation of the treatment
Grade 3 or 4: severe or life-threatening • Grade 3: Prolonged (eg, not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae • Grade 4: Life-threatening consequences; urgent intervention indicated	• Stop the infusion of treatment causing IRR immediately and disconnect infusion tubing from the patient; provide additional appropriate medical measures, and closely monitor until deemed medically stable by the attending physician. Hospitalization and/or close monitoring is recommended • For grade 3 or 4 IRRs, permanent discontinuation of bintrafusp alfa is mandated

After the bintrafusp alfa infusion is interrupted or rate reduced to 50% of previous infusion rate, it must remain decreased for all subsequent infusions

AE, adverse event; irAE, immune-related adverse event; IRR, infusion-related reaction; IV, intravenous; NCI-CTCAE v5.0, National Cancer Institute Common Terminology Criteria for Adverse Events Version 5.0; NSAID, nonsteroidal anti-inflammatory drug.

Merck and GlaxoSmithKline. Data on file.

INTREPID CLINICAL TRIALS™