TABLE A2. Immunosuppressive Agents (continued)

Immunosuppressive Agents	Dosing	Indications	Contraindications and Cautions
Infliximab (anti–TNF-α)	5 mg/kg IV, second dose may be repeated 14 days later	Severe or steroid-refractory colitis, pneumonitis, myocarditis, arthritis, nephritis, uveitis, and hematologic irAEs	Infliximab at doses > 5 mg/kg is contraindicated in moderate to severe heart failure. It is also contraindicated in patients with previous severe hypersensitivity reaction to infliximab or known hypersensitivity to inactive components of infliximab or to any murine proteins. Warning with infliximab includes increased risk of serious infections leading to hospitalization or death. Discontinue infliximab if a patient develops a serious infection. Perform test for latent TB; if positive, start treatment for TB before starting infliximab. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. Cases of fatal HSTCL have been reported in patients treated with TNF blockers including infliximab. All infliximab cases were reported in patients with Crohn's disease or ulcerative colitis, the majority of whom were adolescent or young adult males. All had received AZA or 6-mercaptopurine concomitantly with infliximab at or before diagnosis. https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/103772s5359lbl.pdf
Rituximab (anti-CD20)	375 mg/m^2 once a week × 4 doses	Dermatologic and hematologic irAEs, myositis, encephalitis, IVIG or plasmapheresis-refractory myasthenia gravis	No contraindications. Warnings for rituximab include fatal infusion reactions within 24 hours of rituximab infusion have been reported. Approximately 80% of fatal reactions occurred with the first infusion. Monitor patients and discontinue RITUXAN infusion for severe reactions. Tumor lysis syndrome, severe mucocutaneous reactions, some with fatal outcomes, and PML resulting in death have also been reported. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103705s5367s5388lbl.pdf
Tocilizumab (anti–IL-6)	8 mg/kg administered IV once per month or 162 mg administered SC once per week	irAEs refractory to TNF-α inhibitors	Tocilizumab is contraindicated in patients with known hypersensitivity to tocilizumab. Warning that use of tocilizumab can result in serious infections leading to hospitalization or death including TB, bacterial, invasive fungal, viral, and other opportunistic infections has occurred in patients receiving tocilizumab. If a serious infection develops, interrupt tocilizumab until the infection is controlled. Perform test for latent TB; if positive, start treatment for TB before starting tocilizumab. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125276s114lbl.pdf
Vedolizumab (α4/b7 integrin antagonist)	300 mg IV on weeks 0, 2, 6, and then once every 8 weeks thereafter	Colitis refractory to infliximab or infliximab contraindicated	Vedolizumab is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to vedolizumab or any of its excipients. Warnings for vedolizumab include hypersensitivity reactions (including anaphylaxis); infections—treatment with vedolizumab is not recommended in patients with active, severe infections until the infections are controlled. Although no cases of PML have been observed in clinical trials, JCV infection resulting in PML and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurologic signs or symptoms. https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125476s000lbl.pdf
Ustekinumab (anti–IL-12/IL-23)	Induction: ≤ 55 kg: 260 mg IV as single dose; > 55 kg to 85 kg: 390 mg IV as single dose; > 85 kg: 520 mg IV as single dose Maintenance: 90 mg SC once every 8 weeks; begin maintenance dosing 8 weeks after the IV induction dose	Colitis refractory to all immunosuppression treatments	Ustekinumab is contraindicated in patients who have a significant hypersensitivity to ustekinumab or any of its excipients. Warnings for ustekinumab include risk of infection, malignancies, and hypersensitivity reactions. https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/761044lbl.pdf

(continued on following page)