Quality Innovation Center

Clinical Guideline Flowchart for Treating Psoriasis Patients Using Biologics

The following is a supplementary table for Treating Psoriasis Patients Using Biologics.*

	TNA-α Inhibitor	IL-12/23 Inhibitor	IL-17 Inhibitor	IL-23 Inhibitor
Baseline Screening, Monitoring, and Labs	• Complete blood count (CBC) • Complete Metabolic Profile (CMP) • TB Test (Referral for chest radiograph if necessary) • Hepatitis B and C • HIV test† • Chronic heart failure • Infectious disease specialist referral on a case-by-case basis	• CBC • CMP • TB Test (Referral for chest radiograph if necessary) • Hepatitis B and C • HIV test† • Infectious disease specialist referral on a case-by-case basis	• CBC • CMP • TB Test (Referral for chest radiograph if necessary) • Hepatitis B and C • HIV test† • Infectious disease specialist referral on a case-by-case basis • History of IBD	• CBC • CMP • TB Test (Referral for chest radiograph if necessary) • Hepatitis B and C • HIV test† • Infectious disease specialist referral on a case-by-case basis
Ongoing Monitoring	• Assessment for infections • Non-melanoma skin cancer for those with risk factors (prior history of NMSC and PUVA) especially in those using combination therapy with methotrexate (MTX) • Yearly testing for latent TB in high-risk patients.‡	• Assessment for infections • Non-melanoma skin cancer for those with risk factors • Yearly testing for latent TB screen/test‡	• Assessment for infections (especially mucocutaneous candida) • Non-melanoma skin cancer for those with risk factors • Yearly testing for latent TB screen/test‡ • IBD • Assessment/screen for suicidal ideation (BRO)	• Assessment for infections • Non-melanoma skin cancer for those with risk factors • Yearly testing for latent TB screen/test‡ • Hepatitis B and C§
Time to evaluate for efficacy	• 12-16 weeks • 8-10 weeks (IFX)	• 12 weeks	• 12 weeks	• 12 weeks
Frequency of follow-up	• Quarterly to yearly depending on treatment, response, and tolerability of medication.	• Quarterly to yearly depending on treatment, response, and tolerability of medication.	• Quarterly to yearly depending on treatment, response, and tolerability of medication. • Patients taking BRO may require more frequent follow-up to assess for mood change/depression/suicidal behavior/ideation	• Quarterly to yearly depending on treatment, response, and tolerability of medication.

* Supplementary Information is expert opinion and not part of evidence-based recommendations
† Optional, based on patient history
‡ In non-high-risk patients test should be done at the discretion of physician
§ In patients with risk factors

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Adverse effects	• Infection • Multiple sclerosis (MS)/demyelinating disease (very rare) • Hepatotoxicity (particularly with IFX) (very rare) • Drug-induced lupus erythematosus without renal or Central Nervous System complications (very rare) • Exacerbation or new-onset CHF • Cytopenia (very rare)	• Infection • Hypersensitivity reactions	• Infection • Increased liver transaminases (SEC) • IBD • Candida infections • Neutropenia • Hepatotoxicity • Suicidal Ideation (BRO)	• Infection • Increased liver transaminases
Contraindications	**Relative** • Untreated Hepatitis B infection • History of lymphoreticular malignancy • Active infection (TB or sepsis) • CHF or pre-existing MS **Absolute** • History of an allergic reaction to agent or vehicle • History of (MS)/demyelinating disease	**Relative** • Untreated Hepatitis B • History of lymphoreticular malignancy • Active infection (TB or sepsis) **Absolute** • History of an allergic reaction to agent or vehicle	**Relative** • Active history or current IBD • History of suicidal ideation or behavior (BRO) **Absolute** • History of an allergic reaction to agent or vehicle	**Relative** • Untreated Hepatitis B • History of malignancy • Active infection (TB or sepsis) **Absolute** • History of an allergic reaction to agent or vehicle
Biologics and Vaccines	• Inactivated or "dead" vaccines may be given • Consult with infectious disease specialist for administration of live vaccines • Discontinue all biologic agents before administration of live vaccine • Period before discontinuation is based on physician discretion as well as the period to restart treatment			
Biologic and Surgery	• Biologic therapy can be continued through low-risk surgical procedures • Biologic therapy continuation/discontinuation should be evaluated in a case-by-case basis for moderate to high risk surgical procedures. • Period to discontinue and resume biologic therapy should be determined based on physician discretion.			

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Pregnancy	• Safe in pregnancy and during lactation
	• Safe in men attempting conception with their partner
	• Neonates and infants should be considered immunosuppressed for at least 1-3 mo. post-partum in mothers who have been treated with TNF-α Inhibitors
	  o There is an increased theoretical risk with use during 3rd trimester owing to transplacental transfer of TNF-α inhibitor
	• Exception: CZB has shown minimal to no placental transfer
		• Uncertain safety during pregnancy and lactation
		• Acceptable for men attempting conception with their partner
			• No studies on human pregnancy
			• Animal studies show no harm to fetus with SKB, IXE, or BRO
			  o Higher neonatal deaths observed with higher doses than recommended for IXE.
			• All are likely acceptable in men attempting conception with their partner
			• Presence in human milk has not been studied
				• Unknown safety during pregnancy
				• Presence in human milk has not been studied, however, antibodies are effectively secreted during lactation and caution is recommended

Discontinuation and Re-initiation	• Presence of febrile illness; Uncomplicated infections (based on treating physician discretion) • Treatment can be restarted after full resolution of symptoms and/or signs of infection and the completion of any antibiotic course • Loading dose repetition depends on disease severity, and the number of doses missed. • Consider repeating loading dose upon restarting medication if the patient is flaring and/or if more than 3-4 half-lives have passed since the previous dose.	• Presence of febrile illness; Uncomplicated infections (based on treating physician discretion) • Treatment can be restarted after full resolution of symptoms and/or signs of infection and the completion of any antibiotic course • Loading dose repetition depends on disease severity, and the number of doses missed. • Consider repeating loading dose upon restarting medication if the patient is flaring and/or if more than 3-4 half-lives have passed since the previous dose.	• Presence of febrile illness; Uncomplicated infections (based on treating physician discretion) • Treatment can be restarted after full resolution of symptoms and/or signs of infection and the completion of any antibiotic course • Loading dose repetition depends on disease severity, and the number of doses missed. • Consider repeating loading dose upon restarting medication if the patient is flaring and/or if more than 3-4 half-lives have passed since the previous dose.	• Presence of febrile illness; Uncomplicated infections (based on treating physician discretion) • Treatment can be restarted after full resolution of symptoms and/or signs of infection and the completion of any antibiotic course • Loading dose repetition depends on disease severity, and the number of doses missed. • Consider repeating loading dose upon restarting medication if the patient is flaring and/or if more than 3-4 half-lives have passed since the previous dose.

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Loading Dose	• **ETN:** 50-mg subcutaneous (SC) injection twice weekly for 12 wk • **IFX:** 5mg/kg IV infusion administered in wk 0, wk 2, and wk 6 • **ADA:** 80-mg SC injection (2 x 40 mg at initial dose). Followed by 40-mg SC injection 1 week later • **CZB:** (A) 400 mg or (B) Pts. <90 kg 400 mg initially and at wk 2 and wk 4	**UST** • (a) For patients weighing ≤ 100 kg: 45 mg administered subcutaneously initially and 4 wk later • (b) For patients weighing > 100 kg: 90 mg administered subcutaneously initially and 4 wk later	**SKB** • 300-mg subcutaneous injection at wk 0, wk 1, wk 2, wk 3, and wk 4 **BRO** • 210-mg subcutaneous injection on wk 0, wk 1, wk 2 **IXE** • 160-mg subcutaneous injection followed by 80 mg on wk 2, wk 4, wk 6, wk 8, wk 10, and wk 12	**GUS** • 100-mg subcutaneous injection on wk 0 and wk 4 **TIL** • 100-mg subcutaneous injection on wk 0 and wk 4 **RZB** • 150 mg (two 75 mg injections) subcutaneous injection on wk 0 and wk 4
Maintenance Dose**	**ETN** • 50-mg SC injection once per wk after the first 12 weeks loading **IFX** • 5-mg/kg IV infusion administered every 8 wk [time interval can be modified and dose per kg can be increased according to pt. response]†† **ADA** • 40 mg SC injection every 2 wk **CZB** (A) 400 mg EOW (B) 200 mg EOW	**UST** • (a) Patients ≤ 100 kg: 45 mg administered subcutaneously every 12 wk • (b) Patients > 100 kg: 90 mg administered subcutaneously every 12 wk	**SKB** • 300-mg subcutaneous injection every 4 wk **BRO** • 210-mg subcutaneous injection every 2 wk **IXE** • 80-mg subcutaneous injection every 4 wk after the first 12 weeks loading	**GUS** • 100 mg subcutaneous injection every 8 wk **TIL** • 100 mg administered subcutaneously every 12 wk **RZB** • 150 mg (two 75 mg injections) administered subcutaneously every 12 wk

List of Combination Therapies	• Topical
	  ○ ETN, IFX, ADA
	• Acitretin
	  ○ ETN, IFX, ADA
	• Methotrexate
	  ○ ETN, IFX, ADA
	• Apremilast
	  ○ ETN, IFX, ADA
	• Cyclosporine
	  ○ ETN, ADA
	• NB-UVB
	  ○ ETN, ADA
		• Topical
		  ○ UST
		• Acitretin
		  ○ UST
		• Methotrexate
		  ○ UST
		• Apremilast
		  ○ UST
		• Cyclosporine
		  ○ UST
		• NB-UVB
		  ○ UST
			N/A	N/A

Half-lives (days)	• ETN: 3.5 • IFX: 10 • ADA: 14 • CZB: 14	• UST: 21	• SKB: 27 • BRO: 11 • IXE: 13	GUS: 18 TIL: 23 RZB: 11

** Some patients may need more frequent or increased dosing.
†† Maximum dose is 10-mg/kg every 4 weeks