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 Assessment for 	 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 Assessment for 	 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 Assessment for infections 	 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 Assessment for
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.

[§] In patients with risk factors

 $^{^{*}}$ 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

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	TNA-α Inhibitor	IL-12/23 Inhibitor	IL-17 Inhibitor	IL-23 Inhibitor
Adverse effects Contraindications	 TNA-α Inhibitor 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) 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 	 IL-12/23 Inhibitor Infection Hypersensitivity reactions Relative Untreated Hepatitis B History of lymphoreticular malignancy Active infection (TB or sepsis) Absolute History of an allergic reaction to agent or vehicle 	 IL-17 Inhibitor Infection Increased liver transaminases (SEC) IBD Candida infections Neutropenia Hepatotoxicity Suicidal Ideation (BRO) Relative Active history or current IBD History of suicidal ideation or behavior (BRO) Absolute History of an allergic reaction to agent or vehicle 	IL-23 Inhibitor • Infection • Increased liver transaminases transaminases Barbon Strate • Untreated Hepatitis B • History of malignancy • Active infection (TB or sepsis) Absolute • History of an allergic reaction to agent or vehicle
Biologics and Vaccines	 disease 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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	TNA-α Inhibitor	IL-12/23 Inhibitor	IL-17 Inhibitor	IL-23 Inhibitor
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 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 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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	TNA-α Inhibitor	IL-12/23 Inhibitor	IL-17 Inhibitor	IL-23 Inhibitor
Loading Dose	• ETN: 50-mg	UST	SKB	GUS
	 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 	 (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 	 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 	 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 	 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	mg EOW	. Tarriarl	N/A	N/A
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 		
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

For more information, contact the American Academy of Dermatology: WEBSITE: aad.org



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