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## Biologics for Psoriasis

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Dr. Strowd is from Clinical Associates at Reisterstown, Maryland. The author reports no conflict of interest.

Biologic	Mechanism of Action	Route of Administration	Dosing Regimen	Pivotal PASI Trial Results	Pregnancy Category	Side Effects	Notes
Adalimumab (Humira; AbbVie Inc; Exemptia; Cadila Healthcare Ltd)	Human monoclonal antibody that binds to both soluble and membrane-bound TNF- $\alpha$	SQ injection	80 mg on day 1, then 40 mg every other wk starting 1 wk after initial dose (plaque psoriasis dosing); 40 mg every other week (PsA dosing)	70% achieved PASI 75 at wk 12 (REVEAL, CHAMPION)	B	Reactivation of latent TB or HBV infection, development of skin cancers, infections, worsening of existing heart failure, lupuslike symptoms, positive ANA, demyelinating diseases of the CNS, lymphoma, solid organ tumors, psoriasisiform dermatitis	FDA approved for plaque psoriasis, PsA, AS, Crohn disease, UC, JIA, HS, and RA
Certolizumab (Cimzia; UCB, Inc)	Chimeric antibody that binds to both soluble and membrane-bound TNF- $\alpha$	SQ injection	400 mg at wk 0, 2, and 4, then 200 mg every 2 wk (PsA dosing)	64% showed 20% improvement in PsA at wk 24 (RAPID-PsA)	B	Infections, lymphoma, worsening of existing heart failure, reactivation of latent TB or HBV infection, demyelinating diseases of the CNS	FDA approved for PsA, Crohn disease, RA, and AS; currently in phase 3 clinical trials for plaque psoriasis (CIMPASI I/II, CIMPACT)
Etanercept (Enbrel; Amgen Inc)	TNF- $\alpha$ receptor IgG1 fusion protein that binds to soluble TNF- $\alpha$	SQ injection	50 mg twice weekly for 3 mo, then 50 mg once weekly (plaque psoriasis dosing); 50 mg once weekly (PsA dosing)	49% achieved PASI 75 at wk 12	B	Lupuslike symptoms, positive ANA, demyelinating diseases of the CNS, reactivation of latent TB infection, infections, worsening of existing heart failure, psoriasisiform dermatitis	FDA approved for plaque psoriasis, PsA, RA, JIA, and AS

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Biologic	Mechanism of Action	Route of Administration	Dosing Regimen	Pivotal PASI Trial Results	Pregnancy Category	Side Effects	Notes
Golimumab (Simponi; Janssen Biotech, Inc)	Human monoclonal antibody that binds to soluble and membrane-bound TNF- $\alpha$	SQ injection	50 mg once monthly (PsA dosing)	50% showed 20% improvement in PsA at wk 14 (GO-REVEAL)	B	Infections, lymphoma, worsening of existing heart failure, reactivation of latent TB or HBV infection, demyelinating diseases of the CNS	FDA approved for PsA, RA, AS, and UC; not currently approved for psoriasis but has shown efficacy in off-label treatment of plaque psoriasis
Infliximab (Remicade; Janssen Biotech, Inc)	Chimeric mouse/human monoclonal antibody that binds to both soluble and membrane-bound TNF- $\alpha$	IV infusion	5 mg/kg at wk 0, 2, and 6, then every 8 wk	80% achieved PASI 70 at wk 10 (EXPRESS I/II)	B	Infections, reactivation of latent TB or HBV infection, lupuslike symptoms, positive ANA, demyelinating diseases of the CNS, psoriasisform dermatitis, vitiligo	FDA approved for plaque psoriasis, PsA, Crohn disease, UC, AS, and RA; for treatment of RA, the FDA requires use of concomitant MTX; infliximab antibody formation can occur in up to one-third of patients (use of MTX may decrease infliximab antibody formation)
Ixekizumab (Taltz; Eli Lilly & Company)	Humanized monoclonal antibody that binds to IL-17A cytokine	SQ injection	160 mg at wk 0; 80 mg at wk 2, 4, 6, 8, 10, and 12; then 80 mg every 4 wk	89% achieved PASI 75 by wk 12 (UNCOVER 1)	Unknown	Worsening of existing Crohn disease, infections, reactivation of latent TB infection	Newest FDA-approved biologic medication for psoriasis

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Biologic	Mechanism of Action	Route of Administration	Dosing Regimen	Pivotal PASI Trial Results	Pregnancy Category	Side Effects	Notes
Secukinumab (Cosentyx; Novartis Corporation)	Human monoclonal antibody that binds to IL-17A	SQ injection	300 mg at wk 0, 1, 2, 3, and 4, then 300 mg every 4 wk (plaque psoriasis dosing); with a loading dosage: 150 mg at wk 0, 1, 2, 3, and 4 and every 4 wk thereafter (PsA dosing); without a loading dosage: 150 mg every 4 wk (PsA dosing); if patient continues to have active PsA, consider a dosage of 300 mg	82% achieved PASI 75 by wk 12 (FIXTURE, ERASURE)	B	Worsening of existing Crohn disease, infections, reactivation of latent TB	FDA approved for plaque psoriasis, PsA, and AS
Ustekinumab (Stelara; Janssen Biotech, Inc)	Human monoclonal antibody that binds to the p40 subunit of IL-12 and IL-23	SQ injection given by health care provider	Weight-based dosing: 45 mg for ≤100 kg (220 lb) and 90 mg for >100 kg (220 lb) first 2 doses 4 wk apart, then every 12 wk (plaque psoriasis dosing); 45 mg first 2 doses 4 wk apart, then every 12 wk (PsA dosing)	67% achieved PASI 75 by wk 12 (PHOENIX 1/2)	B	Infections, reactivation of latent TB infection, reversible posterior leukoencephalopathy syndrome, development of skin cancers or solid organ cancers	FDA approved for plaque psoriasis and PsA

Abbreviations: PASI, psoriasis area and severity index; TNF, tumor necrosis factor; SQ, subcutaneous; TB, tuberculosis; HBV, hepatitis B virus; ANA, antinuclear antibodies; CNS, central nervous system; FDA, US Food and Drug Administration; PsA, psoriatic arthritis; AS, ankylosing spondylitis; UC, ulcerative colitis; JIA, juvenile idiopathic arthritis; HS, hidradenitis suppurativa; RA, rheumatoid arthritis; IV, intravenous; MTX, methotrexate.

## SUGGESTED READINGS

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## Practice Questions

1. **Which biologic is administered as an intravenous infusion?**
  - a. adalimumab
  - b. etanercept
  - c. infliximab
  - d. secukinumab
  - e. ustekinumab
  
2. **Which biologic is dosed based on body weight?**
  - a. adalimumab
  - b. etanercept
  - c. infliximab
  - d. secukinumab
  - e. ustekinumab
  
3. **Which biologic has been shown to worsen existing Crohn disease?**
  - a. adalimumab
  - b. etanercept
  - c. infliximab
  - d. secukinumab
  - e. ustekinumab
  
4. **Which biologic is a fusion protein?**
  - a. adalimumab
  - b. etanercept
  - c. infliximab
  - d. secukinumab
  - e. ustekinumab
  
5. **Which biologic has been shown to cause reversible posterior leukoencephalopathy syndrome?**
  - a. adalimumab
  - b. etanercept
  - c. infliximab
  - d. secukinumab
  - e. ustekinumab

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