



## **Indiana Medicaid Therapeutics Committee** **Therapeutic Class Review Summary**

### **Therapeutic class:**

Targeted Immunomodulators

### **Overview:**

Targeted immunomodulators, commonly referred to as biological response modifiers or biologics, are used in the treatment of certain types of immunologic and inflammatory diseases, including rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis. Targeted immunomodulators work by selectively blocking mechanisms involved in the inflammatory and immune response.

Certolizumab, etanercept, adalimumab, anakinra, golimumab, and ustekinumab reduce inflammation and structural damage by blocking the action of cytokines. Certolizumab, etanercept, adalimumab, and golimumab exert their effects by binding specifically to tumor necrosis factor (TNF) and blocking its interaction with cell surface TNF receptors; anakinra and ustekinumab work by blocking the biologic activity of interleukins. Alefacept interferes with the migration, activation, and proliferation of T cells resulting in relief from signs and symptoms.

Golimumab and ustekinumab have longer half-lives and are dosed monthly and every 12 weeks, respectively. Certolizumab and adalimumab are dosed every other week. Etanercept can be dosed once or twice per week, anakinra is dosed once daily, and alefacept is dosed once weekly for 12 weeks. All of these agents are administered subcutaneously.

A disadvantage of the targeted immunomodulators is that they have been associated with the development of serious infections. Bacterial sepsis, tuberculosis, invasive fungal infections, and opportunistic infections have been reported with use of TNF inhibitors; some infections have led to hospitalizations or death. Infections related to anakinra use included cellulitis, pneumonia, and bone and joint infections, rather than opportunistic, fungal, or viral infections. However, many infections associated with use of the targeted immunomodulators have occurred in patients on concomitant immunosuppressive therapy.



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Generic Name	Brand Name	Manufacturer	Generic Available
Alefacept	Amevive <sup>®</sup>	Astellia Pharma	N
Certolizumab pegol	Cimzia <sup>®</sup>	UCB, Inc.	N
Etanercept	Enbrel <sup>®</sup>	Immunex	N
Adalimumab	Humira <sup>®</sup>	Abbott	N
Anakinra	Kineret <sup>®</sup>	Biovitrum	N
Golimumab	Simponi <sup>™</sup>	Centocor Ortho Biotech Inc.	N
Ustekinumab	Stelara <sup>™</sup>	Centocor Inc	N

**Summary:**

Though treatment options vary for immunologic and inflammatory diseases, the goals of therapy remain to improve a patient's sense of well-being and ability to function. Serious and potentially fatal infections remain a concern with the targeted immunomodulators, especially when used with other immunosuppressants. Given that the targeted immunomodulators are not first-line agents, a prior authorization process may be warranted to ensure these products are utilized according to their place in therapy.