

**Indiana Hoosier Healthwise
Specialty Pharmacy Changes
September 2008 DUR Board Presentation**

Addition of Clinical Criteria to Specialty products

Product	Rationale	PA Criteria
AMEVIIVE	To ensure appropriate dosing and utilization for the medical need	Patient must meet all of the following: 1. Patient has a diagnosis of chronic moderate to severe plaque psoriasis with either of the following: a. Greater than 10% of body surface area with plaque psoriasis; or b. Less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia) 2. Failure of phototherapy or other systemic therapies to achieve an adequate clinical response, or a medical contraindication to the use of phototherapy or other systemic therapies (e.g. methotrexate) 3. Disease is not controlled with topical therapy 4. Patient has none of the following present: a. Currently receiving other immunosuppressive therapy or phototherapy b. Patient is HIV positive c. CD4+ T lymphocyte count < 250 cells per microliter d. History of recurrent infection, or current chronic infection or clinically important infection, or positive tuberculin skin test. e. History of systemic malignancy within last 5 years f. Pregnant women or nursing mothers g. Age < 18 years
CIMZIA	To ensure appropriate dosing and utilization for the medical need	Cimzia® (certolizumab pegol) may be approved in patients who meet the following criteria: I. Patient is 18 years of age or older; AND II. Patient has a diagnosis of moderate to severe Crohn's Disease; AND III. Patient has had an inadequate response or is unable to tolerate

		<p>conventional therapies [e.g. sulfasalazine, mesalamine products, corticosteroids, immunosuppressants (6-mercaptopurine, azathioprine, cyclosporine, or methotrexate)]; AND IV. Patient has had an inadequate response or is intolerant to Remicade (infliximab) V. Cimzia® (certolizumab pegol) is considered NOT medically necessary for patients with any of the following:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Individuals with CHF who develop new symptoms or worsening symptoms of preexisting CHF <input type="checkbox"/> Tuberculosis or other active serious infections, including chronic or localized infections <input type="checkbox"/> Individuals who have not had a tuberculin skin test to rule out latent tuberculosis <input type="checkbox"/> Multiple sclerosis or other demyelinating neurological disease <input type="checkbox"/> Concurrent administration of live (including attenuated) vaccines with certolizumab pegol (Cimzia®) <input type="checkbox"/> Currently receiving other TNF blocking agents or anakinra (Kineret®) <input type="checkbox"/> Any other indication not listed
TOBI	To ensure appropriate dosing and utilization for the medical need	TOBI would be approved in patients with Cystic fibrosis where sputum is colonized with Pseudomonas