

## HUMIRA® (adalimumab) Medicaid Testimony

Updated September 24, 2015

Note to MOSL: It is mandatory to read all of the boxed sections of this testimony; unboxed sections may also be included as situation and time permits.

Hello. My name is Dr. \_\_\_\_ from Medical Affairs at AbbVie. Thank you for the chance today to speak about HUMIRA. Please review the full PI at [www.rxabbvie.com](http://www.rxabbvie.com) for comprehensive safety & efficacy data.

Humira recently added a 9<sup>th</sup> indication to its profile and is approved for the treatment of moderate to severe Hidradenitis Suppurativa or HS.

This follows the currently approved indications for Humira which include:

1. Moderate to Severe Rheumatoid Arthritis with proven key endpoints of halting joint destruction, improving functional status and improving signs and symptoms.
2. Moderate to Severe Juvenile Idiopathic Arthritis (age 2 years and older)
3. Psoriatic Arthritis- reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function.
4. Ankylosing Spondylitis
5. Moderate to Severe Crohn's Disease-approved to induce and maintain remission
6. Moderate to Severe Chronic Plaque Psoriasis
7. Moderate to Severe Ulcerative Colitis: inducing and sustaining clinical remission
8. Moderate to Severe Pediatric Crohn's Disease (age 6 years and older)

The majority of HUMIRA utilization is in RA, Crohn's Disease, and Psoriasis

HS is a painful, chronic relapsing, debilitating inflammatory skin disease characterized by painful inflamed nodules in the apocrine gland-bearing regions (armpits, genital area, groin, breasts and buttocks/anus) that can progress to abscesses, sinus tracts and scarring. The estimated prevalence of confirmed HS is 127.8/100,000 in the United States, of which, an estimated that 40.3% are classified as moderate-to-severe HS based on a Hurley Score of 2 or 3. The disease is often seen by non-dermatologists and clinical experience suggests that it is under-recognized.

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The efficacy and safety of HUMIRA in patients with moderate to severe HS was studied in a total of 633 subjects in two 36-week, randomized, double-blind placebo controlled, phase 3, trials (PIONEER I and II). Both studies evaluated Hidradenitis Suppurativa Clinical Response (HiSCR) at Week 12. HiSCR was defined as at least a 50% reduction in total abscess and inflammatory nodule count with no increase in abscess count and no increase in draining fistula count relative to baseline. PIONEER I: At week 12, significantly more adalimumab-treated patients (41.8%) compared with placebo-treated patients (26.0%) achieved a HiSCR response ( $P < 0.01$ ). Adverse events were similar between the 2 groups. PIONEER II: At week 12, significantly more adalimumab treated patients (58.9%) compared with placebo treated patients (27.6%) achieved a HiSCR ( $p < 0.001$ ). Adverse events were similar between the 2 groups.

In both trials, significantly more patients randomized to HUMIRA achieved the primary endpoint of HiSCR compared with those randomized to placebo.

The safety profile for subjects with HS treated with HUMIRA weekly was consistent with the every other week dosing and the known safety profile of HUMIRA.

Currently, HUMIRA is the only FDA approved treatment regimen for HS.

### Safety:

With over 70 global clinical trials enrolling over 23,000 patients, HUMIRA has a well-defined, published benefit/risk database. The majority of the safety data come from the larger RA population. All TNF antagonists carry similar boxed warnings regarding serious infections, TB, and malignancies. Patients starting any anti-TNF, including Humira, should be screened for TB and carefully monitored for serious events.

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### Dosing:

The recommended maintenance dose of HUMIRA for adults is 40mg SQ every other week with some indications requiring a loading dose. In HS, the recommended dose is 40 weekly following same loading dose schedule utilized for CD/UC Initial dose (Day 1): 160 mg (given as four 40 mg injections on Day 1 or as two 40 mg injections per day on Days 1 and 2) Second dose two weeks later (Day 15): 80 mg (two 40 mg injections in one day). Third (Day 29) and subsequent doses: 40 mg every week.

### Summary:

In summary, proven sustained efficacy, well established safety profile, and maintenance dosing across a wide range of indications are reasons why I respectfully urge the Committee to maintain preferred status of HUMIRA on the PDL.

Thank you.