Indian Health Service
National Pharmacy and Therapeutics Committee
Formulary Brief: ***Treatment of Psoriasis***
-February 2018-

Background:

Psoriasis is a chronic inflammatory disease affecting approximately 2-3% of the population worldwide with affected patients frequently remaining undiagnosed or untreated. Approximately 80% of patients with psoriasis have mild-to-moderate disease, whereas 20% have moderate-to-severe disease. Psoriatic arthritis has been reported in up to 42% of patients with psoriasis and can progress to significant deforming disease. Comorbid conditions include: obesity, type 2 diabetes, metabolic syndrome, heart disease, lymphoma, and depression, as well as Crohn's disease and possibly multiple sclerosis. Following the clinical and pharmacoeconomic review of the treatment(s) of psoriasis at the 2018 Winter Meeting, the NPTC voted to **add high-potency topical corticosteroids (Class I and II)** and a **topical vitamin D analogue, any** to the IHS National Core Formulary.

Discussion:

Because 80% of patients have limited disease, treatment may be managed topically with steroids, vitamin D analogues, calcineurin inhibitors & retinoids. However, use of systemic agents may be considered in even limited disease (≤5% Body Surface Area (BSA)) depending on the cosmetic sensitivity of the affected region, e.g., scalp, face, hands, feet or genitalia and/or the presence of concomitant psoriatic arthritis.

Patients may be candidates for systemic agents or ultraviolet (UV)-based therapies when patient has more extensive involvement >5-10% BSA. The decision for systemic or UV-based therapy relies on the consideration of patient comorbidities, pregnancy or ability to become pregnant, potential drug-drug interactions, family history of contraindicated conditions, and social issues such as smoking and alcoholism. Given the significant risk of adverse events with all systemic agents, caution is recommended for patients who are non-compliant and/or unreliable (i.e., substance abuse). While UV-based therapy is considered first line for moderate-to-severe psoriasis, treatment is often limited by the need for a site that offers such therapy, requirements for 2-to-3 visits per week, and potential for increased risk of skin cancers in select populations. The following website is a searchable directory from the American Academy of Dermatology of healthcare providers offering UV-based phototherapy by location: https://www.aad.org/find-a-derm.

The traditional systemic agents used for psoriasis include methotrexate, cyclosporine, and acetretin. All of the traditional systemic agents are effective for psoriasis but have serious side effects that may preclude their use. Their advantages over new biologic therapies are low cost and more convenient administration (i.e., do not require injection). Limitations to both methotrexate and cyclosporine include worsening of preexisting conditions in patients with liver disease (methotrexate), hypertension and renal insufficiency (cyclosporine), tolerability, and possible drug-drug interactions. Biologic therapy, of which the IHS National Core Formulary includes two TNF-alpha inhibitors, offers significant advantages to patients with complex medical histories on multiple medications. In general, there are no relevant drug interactions with the biologics and they are considered to have fewer safety issues as compared with traditional systemic agents.

The IHS National Core Formulary currently includes methotrexate, cyclosporine, etanercept & adalimumab, all of which are approved treatments for moderate-to-severe psoriasis and psoriatic arthritis. Currently lacking are topical medications approved for mild-to-moderate disease, including Class I and Class II topical steroids which decrease the risk of hypothalamic-pituitary-adrenal suppression and precipitation of erythrodermic psoriasis, which are associated with oral and intravenous corticosteroids. In addition to the TNF-alpha inhibitors, the advent of Interleukin-12 and -23 inhibitors (ustekinumab, guselkumab) and Interleukin-17 inhibitors (secukinumab, ixekinumab, brodalumab) provide higher Psoriasis Area and Severity Index score improvements with reductions in number of injections per year. Finally, apremilast, a PDE-4 inhibitor, is advantageous as it does not carry an increased risk of serious infection as biologics and, like traditional systemic medications, comes in an oral form for those patients who may be averse to injectable therapies.

Findings/Conclusions:

Medications currently on the IHS National Core Formulary for psoriasis have largely grown out of systemic treatments primarily used for rheumatoid arthritis and other rheumatologic conditions and thus is not presently positioned to optimally treat a relatively common dermatologic condition. The clinical review identified therapeutic opportunities for NCF inclusion that meet the standard of care for management of psoriasis, namely class I and II "high-potency" topical corticosteroids (with both available for scalp use) and a topical vitamin D analogue. Topical calcineurin inhibitors and vitamin D analogues as steroid sparing agents are beneficial for patients with facial and/or inverse psoriasis. On the systemic arm, both acetretin and the novel PDE-inhibitor, apremilast offer an oral agent to those who are injectable averse. Finally, both medications would provide non-immunosuppressing alternatives for patients with concomitant HIV or are at increased risk for infection due to poorly-controlled diabetes. The treatment armamentarium for psoriasis in the realm of biologics has many options that are largely limited by overall cost.

If you have any questions regarding this document, please contact the NPTC at IHSNPTC1@ihs.gov. For more information about the NPTC, please visit the NPTC website.

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