INDIAN HEALTH SERVICE

National Pharmacy & Therapeutics Committee

Fall 2020 NPTC Meeting (UPDATE)

-November 2020-

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) held its Fall 2020 virtual meeting on November 3-4, 2020. All 12 IHS Areas were represented. IHS clinical subject matter experts providing presentations included Lori Raney, MD (Psychiatry), Gwendolyn Grant, MD (Rheumatology) and LCDR Jeannie Hong, PharmD. Affiliates from the Department of Defense, Veterans Administration, Federal Bureau of Prisons and U.S. Coast Guard provided information on formulary updates, clinical experiences, and future meeting topics from their respective agencies. The NPTC values the relationships with its field experts, subject matter experts, and federal partners and appreciates the opportunity to host this virtual meeting through the Oklahoma City Area IHS Office.

The Fall 2020 meeting agenda included reviews of COVID-19 vaccine candidates & ACIP-recommended vaccines during the COVID-19 pandemic, antiarrhythmic agents for atrial fibrillation, long-acting antipsychotic medications, pharmacotherapies for hepatic encephalopathy, Janus kinase and interleukin 12/23 inhibitors, and biosimilar products for rheumatoid arthritis.

The resulting action(s) from the NPTC meeting were as follows:

1. A comprehensive review of COVID-19 vaccine candidates & ACIP-recommended vaccines during the COVID-19 pandemic was provided to the Committee. Classical and next-generation vaccine platforms were detailed as were processes relating to vaccine clinical trials, including assessment of efficacy and safety outcomes. Published trial characteristics from leading vaccine candidates (e.g., BNT-162b2, mRNA-1273, AZD-1222, Ad26.COV2.S) were focal points for the presentation. Elements of the IHS Vaccine Task Force Safety & Monitoring Team action plan, NPTC vaccine-related efforts, the Vaccine Adverse Event Reporting System and the importance of promoting routine vaccination were also discussed.

2. A drug class review of Antiarrhythmic Agents for Atrial Fibrillation was delivered. *Presently, only digoxin is named to the National Core Formulary (NCF) within this class, although its primary use typically falls outside this indication.* Review of the Class IA, IC and III antiarrhythmics addressed key issues including rate vs. rhythm control, which rhythm drug to use, and catheter ablation comparatively. Clinical practice guidelines and Cochrane reviews were key to the analysis. Agency-specific pharmacoepidemiologic, pharmacovigilance and pharmacoeconomic data added value in the ultimate decision. As a result, **no modifications were made to the NCF**.

3. A drug class review of Long-acting Injectable Antipsychotic Agents (LAAs) was also presented to the NPTC. *The current NCF lists "atypical antipsychotic agent", noting that any medication within this drug class can be used.* Characteristics of both the first- and second-generation LAAs were scrutinized. Clinical experience and key findings/outcomes from both meta-analyses and practice guidelines offered support for these agents. IHS medication procurement, utilization trends and pharmacovigilance data were used to broaden perspective. Following the analysis, the NPTC voted to **ADD (1) aripiprazole lauroxil and (2) haloperidol decanoate to the NCF**.

4. A clinical review of pharmacotherapies for Hepatic Encephalopathy was performed. *Currently, lactulose is listed on the NCF.* The evidence review focused primarily on non-absorbable disaccharides (lactulose, lactitol), rifaximin, and the combination. Multiple Cochrane reviews

and published randomized, controlled trials supported the role of rifaximin in clinical efficacy, safety and mortality. Various national and international guidelines also endorsed rifaximin (with guidance for use). Value-added benefit was provided through review of agency-wide data including pharmacoepidemiologic and pharmacoeconomic trends. As a result, the NPTC voted to **ADD rifaximin** to the NCF, ***after failure of or intolerance to lactulose monotherapy as indicated for hepatic encephalopathy***.

5. A drug class review of Janus Kinase (JAK) and Interleukin 12/23 Inhibitors was provided. *Neither class of drugs is represented on the NCF presently.* Both classes of medications are relatively newer to market and have few within-class agents and/or approved indications. Clinical outcomes, when compared to standard-of-care or in head-to-head studies, appear to demonstrate favorability towards the newer agents which offer various advantages comparatively. Clinical practice guidelines however continue to recognize these drugs as second- or third-line treatment options. IHS procurement, utilization and pharmacovigilance data were also considered in the decision. **No modifications were made to the NCF.**

6. A drug class review of Biosimilar Products for Rheumatoid Arthritis was delivered, with particular attention given to the commercially-available biosimilars of infliximab and rituximab. *Currently, no biosimilar products are named to the NCF.* Published literature on biosimilar outcomes (in both treatment-naïve and "switched" patients) and position statements from both U.S. and European-based Rheumatologic medical organizations were reviewed. Of note, internal IHS facility-specific data was also shared, describing single-site experiences and outcomes with multi-year use of biosimilar products. Agency utilization and procurement data in concert with safety data from the NPTC Pharmacovigilance Program were also presented for committee review. Ultimately, **no modifications were made to the NCF.**

7. An abbreviated review of the Glucagon-Like Peptide-1 Receptor Agonists on the NCF (*dulaglutide, liraglutide, semaglutide*) was presented. The most recent NPTC review of these agents occurred in November 2019, during which the NPTC found relative equivalency among these 3 agents. Following a brief clinical and pharmacoeconomic review, which included IHS procurement updates, the NPTC voted to **REMOVE dulaglutide from the NCF.**

***The next NPTC meeting will be the Winter 2021 Meeting scheduled for January 19-20, 2020. The meeting agenda will include reviews of (1) Hyperthyroidism, (2) Glucagon products, (3) Acute Migraine Treatments, (4) Anti-Emetic Agents, (5) the Heplisav-B vaccine, (6) and a tentative "OPEN" topic, held for COVID-19-related issues as needed.*

For more information about the NPTC or the National Core Formulary, please visit the NPTC website.