INDIAN HEALTH SERVICE
National Pharmacy & Therapeutics Committee
Fall 2023 NPTC Meeting Update
=October 2023=

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) held its Fall 2023 meeting on October 24-25, 2023 in Phoenix, AZ. All 12 IHS Areas were represented. Nina Brahme, PhD (FDA Office of Biologics and Biosimilars), Carmen Licavoli Hardin (IHS Division of Diabetes Treatment and Prevention) and Jean Howe, MD (IHS Chief Clinical Consultant for Obstetrics & Gynecology) provided subject matter expertise during the meeting. Affiliates from the U.S. Department of Defense and U.S. Coast Guard provided information on formulary updates, clinical experiences, and 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 formulary management meeting at the Phoenix Area IHS Office.

The Fall 2023 NPTC Meeting agenda included pharmacotherapeutic reviews of (1) Biosimilars and Interchangeability, (2) Adalimumab Biosimilars, (3) Diabetic Foot Ulcers, (4) Glucagon-Like Peptide-1 (GLP1) Receptor Agonists and dual GLP1/Glucose-dependent Insulinotropic Polypeptide (GIP) Receptor Agonists in Type 2 Diabetes Mellitus and Obesity, (5) Nicotine Dependence, (6) Polycystic Ovary Syndrome, and (7) Insulin detemir (Levemir®).

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

1. A regulatory review of Biosimilars and Interchangeable biosimilars was provided by the FDA to the Committee, specifically addressing scientific, regulatory and clinical considerations for health care providers. Scientific concepts, regulatory framework and case examples relating to the development and utilization of biosimilars were detailed, including key differences in interchangeable biosimilar labeling and use. Provider resources and education/outreach materials were also shared. Following this review, the NPTC made **no modifications** to the National Core Formulary (NCF).

2. A pharmacotherapeutic review of Adalimumab biosimilars was also delivered to the Committee. *Current medication(s) listed on the NCF relevant to this review and currently named to the NCF include(s) adalimumab -or- etanercept.* Supporting evidence for adalimumab biosimilar use from both U.S. and international clinical guidelines was shared, as were findings from meta-analyses and comparative studies of commercially available adalimumab biosimilars. Agency drug procurement trends and costs from the IHS National Supply Service Center (NSSC) were also included. Following deliberation (and in consultation with NSSC staff), the Committee temporarily **tabled any motion(s)** to allow NSSC to aid in identifying optimal, value-based adalimumab biosimilar products.

3. A clinical review of Diabetic Foot Ulcer (DFU) management was provided at the meeting. *Medication(s) listed on the NCF relevant to this condition and currently named to the NCF include(s) moisturizers (both cream- and petroleum-based) and the antibiotics, amoxicillin-clavulanic acid, cephalexin, ciprofloxacin, clindamycin, clotrimazole, doxycycline, fluconazole, and trimethoprim-sulfamethoxazole.* Guidelines from the International Working Group of the Diabetic Foot served as the primary resource and were profiled explicitly. Identification, grading, treatment and prevention of DFUs were reviewed. Agency pharmacoeconomic utilization/trend data added scope. Following review and deliberation, the NPTC made **no modifications** to the NCF.

4. A pharmacotherapeutic review of GLP1 and GLP1/GIP Receptor Agonists was also detailed, with focus on use in patients with Type 2 Diabetes Mellitus (T2DM) and/or obesity. *Medication(s) listed on the NCF relevant to these conditions and currently named to the NCF include(s) liraglutide and semaglutide.* Practice guidelines from the American Diabetes Association, American Gastroenterological Association, American Academy of Pediatrics and Endocrine Society served as primary sources of guidance for the presentation. Published comparative clinical studies of liraglutide, semaglutide and tirzepatide for both obesity and T2DM were critiqued. Other non-incretin medications indicated for obesity were also reviewed. Pharmacoeconomic utilization data and trends for IHS were given, adding scope to this review. Following evaluation and deliberation, the NPTC voted to (1) **REMOVE phentermine-topiramate**, (2) **REMOVE liraglutide**, and (3) **ADD semaglutide (Wegovy®) with recommended local adoption of criteria for use** to the NCF.

5. A pharmacotherapeutic review of Nicotine Dependence (including e-cigarettes) was presented to the Committee. *Medication(s) listed on the NCF relevant to this condition and currently named to the NCF include(s) bupropion, various nicotine replacement therapies (i.e., gum, inhaler, lozenge, nasal spray, and patch) and varenicline*. Guidance from the Agency for Healthcare Research and Quality, American Thoracic Society, and U.S. Centers for Disease Control and Prevention were outlined. Key outcomes from numerous Cochrane Reviews, meta-analyzes and randomized controlled trials were also profiled, which included pregnant and pediatric populations. Utilization and trends from IHS pharmacoeconomic analyses were also presented. As a result of the evaluation, the NPTC made **no modifications** to the NCF.

6. A clinical review of Polycystic Ovary Syndrome (PCOS) was also delivered. *Medication(s) relevant to this condition and currently named to the NCF include(s) combination oral contraceptives, finasteride, letrozole, metformin, pioglitazone, semaglutide, and spironolactone*. The International Evidence Based Guideline for the Assessment and Management of PCOS, American Association of Clinical Endocrinologists and International Consortium of Paediatric Endocrinology documents served as the primary sources of clinical guidance for PCOS management. Published findings of both non-drug and drug-based therapies derived from Cochrane Reviews and meta-analyses were highlighted. Following the clinical review, the NPTC made **no modifications** to the NCF.

7. Lastly, an abbreviated pharmacoeconomic review of insulin detemir (Levemir®) was presented to the Committee. *Medication(s) relevant to this review and currently named to the NCF include(s) any insulin glargine product (including glargine biosimilars)*. Recent clinical evaluations from the NPTC on long-acting insulins were reviewed along with IHS pharmacoeconomic data, including newly updated value-based considerations. Following the review, the NPTC voted to **REMOVE insulin detemir** from the NCF.

***The next scheduled NPTC meeting will be the Winter 2023 Meeting on January 30-31, 2024 in Phoenix, AZ. The meeting agenda will include reviews of (1) Opioid Analgesic Stewardship, (2) Medication-Based Treatment of Opioid Use Disorder, (3) Naloxone Update (including OTCs), (4) Medical Cannabis, (5) Low Back Pain, and (6) CGRPs and 5HT1F receptor agonists in Migraines.*

===NEW=== (located on the IHS NPTC "Meetings Schedule" webpage)

Submit Feedback for upcoming NPTC Scheduled Meeting Topics: *The purpose of this form is to collect feedback and/or recommendations regarding scheduled agenda topics for upcoming National Pharmacy and Therapeutics Committee meetings from Indian Health Service (IHS) clinicians working at Federal, Tribal or Urban Indian Organization programs/sites/facilities. Input on topics for upcoming review can include potential medications for addition or deletion from the IHS National Core Formulary (NCF).*

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