

INDIAN HEALTH SERVICE National Pharmacy & Therapeutics Committee **Summer 2023 NPTC Meeting Update** =August 2023=



The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) held its Summer 2023 meeting on August 1-2nd, 2023 in Nashville, TN. All 12 IHS Areas were represented. Jean Howe, MD, (IHS Chief Clinical Consultant for Obstetrics & Gynecology), Jon Iralu, MD, (IHS Chief Clinical Consultant for Obstetrics & Gynecology), Jon Iralu, MD, (IHS Chief Clinical Consultant for Infectious Disease), CDR Tina Pattara-Lau, MD, (IHS Maternal Child Health Consultant) and CDR Dinesh Sukhlall, PharmD (IHS National Pharmacy Council, Antimicrobial Stewardship Chair) provided subject matter expertise during the meeting. Affiliates from the U.S. Department of Defense, U.S. Coast Guard and Federal Bureau of Prisons 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 clinical formulary management meeting at the Nashville IHS Area Office.

The Summer 2023 NPTC Meeting agenda included operational and/or pharmacotherapeutic reviews of (1) the IHS E3 Vaccine Strategy, (2) OTC norgestrel (Opill[®]), (3) COVID-19 Prevention and Treatment, (4) Prevention of Respiratory Syncytial Virus (RSV), (5) Influenza Prevention and Treatment, (6) Antimicrobial Stewardship, and (7) Subcutaneous, depot medroxyprogesterone acetate injection.

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

- 1. An overview of the <u>IHS E3 Vaccine Strategy</u> was provided to the Committee. Details provided in the presentation included the strategic initiative's mission, goals and objectives, vaccine trends, operational plan, available resources, timeline, examples of best practices, and messaging efforts.
- 2. A pharmacotherapeutic review of OTC norgestrel 0.075mg tablet (Opill®) was also delivered to the Committee. Current medication(s) listed on the IHS National Core Formulary (NCF) relevant to this review include(s) (1) ethinyl estradiol/etonogestrel vaginal ring; (2) ethinyl estradiol/etonogestrel transdermal; (3) etonogestrel, implant; (4) intrauterine device, copper; (5) intrauterine device, levonorgestrel; (6) levonorgestrel (Plan B One-Step®); (7) medroxyprogesterone acetate, injection; (8) medroxyprogesterone, oral; (9) oral contraceptive pill, extended cycle; (10) oral contraceptive pill, monophasic: 20mcg EE (low); (11) oral contraceptive pill, monophasic: 30-35mcg EE (medium); (12) oral contraceptive pill, progestin only; (13) oral contraceptive pill, triphasic and (14) ulipristal. Findings from the FDA's Briefing Document and Decisional Memorandum on the Opill® were detailed. Support from the American Medical Association and American College of Obstetrics & Gynecology (ACOG) for an OTC progestin-only pill was also recognized. Agency analyses of drug procurement trends and cost of prescription for progestin-only contraceptive pills were provided. As a result, the NPTC voted to (1) ADD "norgestrel 0.075mg OTC tablets (Opill®)" to the NCF. Additionally, the NPTC voted to (2) MODIFY language to the currently-named "Progestin-only pills, any product" on the NCF to now include "Progestin-only pills, any prescription product".
- 3. A pharmacotherapeutic update of <u>COVID-19 Prevention and Treatments</u> was provided at the meeting. *Currently, no medications for the treatment or prevention of COVID-19 infection are listed on the NCF.* Guidelines from the National Institutes of Health, Infectious Diseases Society of America (IDSA), National Institute for Health and Care Excellence, as well as several Cochrane Systematic Reviews and recently-published meta-analyses were profiled. Agency pharmacovigilance and pharmacoeconomic utilization/trend data added scope. Following review and deliberation, the NPTC voted to ADD "nirmatrelvir/ritonavir (Paxlovid®)" to the NCF.

- 4. A therapeutic review of <u>RSV Prevention</u> was also detailed, with particular focus on palivizumab, and the two recently approved vaccines and long-acting monoclonal antibody, nirsevimab. *Currently, no medications for the prevention of RSV are listed on the NCF.* Guidelines from the American Academy of Pediatrics (AAP) and the CDC Advisory Committee on Immunization Practices (ACIP) served as primary sources of guidance for the presentation. Agency pharmacovigilance and pharmacoeconomic utilization/trend data were given, adding scope to the review. Following evaluation and committee deliberation, the NPTC voted to ADD "Long-acting monoclonal antibodies, All ACIP-recommended" to the NCF.
- 5. A pharmacotherapeutic review of <u>Influenza Prevention and Treatment</u> was presented to the Committee. *Medication(s) listed on the NCF relevant to this condition include(s) oseltamivir*. Multiple guidelines were reviewed including those from the AAP, ACOG, CDC, and IDSA. Agency pharmacovigilance and pharmacoeconomic utilization/trend data were also shared. As a result of the comprehensive evaluation and analyses, the NPTC made **no modifications** to the NCF.
- 6. A clinical review of <u>Antimicrobial Stewardship</u> was also delivered. *Medication(s) relevant to this condition and currently named to the NCF include(s) amoxicillin, amoxicillin-clavulanate, azithromycin, cefalexin, cefdinir, cefixime, ceftriaxone, ciprofloxacin, clindamycin, doxycycline, metronidazole, nitrofurantoin, penicillin G benzathine, penicillin V potassium, rifampin, sulfamethoxazole-trimethoprim, tinidazole, vancomycin (oral).* Stewardship principles and guidance from the CDC's Core Elements of Antibiotic Stewardship, The Joint Commission, IDSA and The Society for Healthcare Epidemiology of America were central to this review. Agency pharmacovigilance data was also provided relative to antibiotic use. Following review, the NPTC made **no modifications** to the NCF.
- 7. Lastly, a pharmacotherapeutic review of <u>Subcutaneous</u>, <u>depot medroxyprogesterone acetate</u> <u>injection (DMPA-SC)</u> was provided to the Committee. *Medication(s) relevant to this condition and currently named to the NCF include those aforementioned in Item #2 (page 1)*. The CDC's 2021 Morbidity and Mortality Weekly Report entitled "Update to U.S. Selected Practice Recommendations for Contraceptive Use: Self-Administration of Subcutaneous Deport Medroxyprogesterone Acetate" was foundational in the clinical review. Outcomes from multiple published trials and IHS facility data on DMPA-SC use were also provided. Pharmacovigilance and pharmacoeconomic utilization/trend data were also presented. Following this review, the NPTC voted to MODIFY language to the currently-named "Medroxyprogesterone acetate, injection" to now include "Medroxyprogesterone acetate, injection (*IM and SC formulations*)" on the NCF.

*The next scheduled NPTC meeting will be the Fall 2023 Meeting on October 24-25, 2023 in Phoenix, AZ. The meeting agenda will include reviews of the (1) GLP1/GIP Agonists in T2DM and Obesity, (2) Diabetic Foot Ulcers, (3) Biosimilars & Interchangeability, (4) Adalimumab Biosimilars, (5) Tobacco/Nicotine Cessation, and (6) Polycystic Ovary Syndrome (PCOS).

===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).