INDIAN HEALTH SERVICE
National Pharmacy and Therapeutics Committee
Formulary Brief: ***HIV Treatment Update***
- April 2026-

Background:

During its spring 2026 meeting, the National Pharmacy and Therapeutics Committee (NPTC) reviewed current recommendations regarding treatments for human immunodeficiency virus (HIV). Prior to this meeting, the IHS National Core Formulary included, for HIV treatment, both bictegravir/emtricitabine/tenofovir alafenamide and dolutegravir/abacavir/lamivudine, as well as emtricitabine/tenofovir disoproxil fumarate for pre-exposure prophylaxis (PrEP). The National Core Formulary also included dolutegravir as part of a regimen for HIV treatment in pregnancy, and raltegravir for use as part of a post-exposure prophylaxis (PEP) regimen. Following comprehensive review and deliberation, the NPTC voted to **REMOVE (1) dolutegravir/abacavir/lamivudine, (2) dolutegravir, and (3) raltegravir** from the National Core Formulary.

Discussion:

HIV Treatment: Guidelines from several major institutions support the continued use of bictegravir/emtricitabine/tenofovir alafenamide as first-line treatment for HIV infection. These include the United States (U.S.) Department of Health and Human Services, the International Antiviral Society—USA, the European AIDS Clinical Society, and the British HIV Association.[1-4] None of these guidelines recommend dolutegravir/abacavir/lamivudine as first-line treatment. For guidelines that recommend same-day initiation of antiretroviral therapy, this may be due in part to the common recommendation to obtain HLA-B*5701 testing prior to starting any treatment containing abacavir, which can cause a serious hypersensitivity reaction in patients who are positive for that serotype.

Regarding the *efficacy* of bictegravir/emtricitabine/tenofovir alafenamide, i.e. how well it works in randomized controlled trials (RCTs), a systematic review and meta-analysis (SRMA) of RCTs compared bictegravir/emtricitabine/tenofovir alafenamide to other complete regimens, most of which included dolutegravir.[5] This included 3 trials among treatment-naïve patients, and 4 among patients who were already virologically suppressed, for a total of 7 trials with approximately 3,500 participants. For a primary outcome of virologic suppression, defined as fewer than 50 copies of HIV/mL, this SRMA reported no difference in the odds of this event (OR 1.01; 95% CI 0.79-1.30).

Regarding the *effectiveness* of bictegravir/emtricitabine/tenofovir alafenamide, i.e. how well it works in routine clinical practice, a SRMA of observational studies reported that, among about 500 treatment-naïve participants with 48-week viral load data in 3 observational studies, 97% achieved virologic suppression.[6] Only 5% of participants stopped the medication, and only 2% stopped due to adverse effects. Similarly, among about 4,900 treatment-experienced participants with 48-week viral load data in 9 observational studies, 95% achieved virologic suppression. Only 3% stopped the medication, and only 1% stopped due to adverse effects.

For HIV treatment, the degree to which a regimen is *forgiving* of non-adherence has long been an important consideration, with early combination regimens requiring adherence of 95% or greater to maintain viral suppression. A non-systematic review, which appears to be based on individual participant data supplied by the drug's manufacturer, meta-analyzed RCT data to allow the combination across trials specifically of participants with poor adherence, defined as less than 85% adherence estimated based on pill counts.[7] After 144 weeks of follow-up, among participants randomized to bictegravir-based treatment, 37 of 38 participants (97%) with poor adherence achieved virologic suppression, defined as <50 copies/mL. This was compared to dolutegravir-based regimens among poorly adherent patients who only achieved 82% virologic suppression.

Weight gain is a common side effect of antiretroviral therapy, and not solely due to a "return to health" effect. In long-term follow-up data on participants in 2 RCTs, investigators report that, after ~4.6 years of follow-up, cumulative weight gain since randomization ranged from 5.4-6.8 kilograms across 4 arms (2 from each RCT).[8] No differences between patients who started on a bictegravir-based regimen and those who started a dolutegravir-based regimen and then switched to bictegravir-based regimen were observed.

HIV Pre-Exposure Prophylaxis: The National Core Formulary currently includes emtricitabine/tenofovir disoproxil fumarate, and this medication continues to be recommended for this indication by the U.S. Centers for Disease Control and Prevention (CDC).[9]

HIV Post-Exposure Prophylaxis: The National Core Formulary included raltegravir, to be added to emtricitabine/tenofovir disoproxil fumarate, for use as post-exposure prophylaxis (PEP) after a needlestick injury, or sexual exposure. However, the relevant guideline, updated last year for the first time since 2013, now recommends bictegravir/emtricitabine/tenofovir alafenamide as the first-line agent for most patients for this indication.[10] The guideline notes that this recommendation changed even though the authors found no evidence of decreased efficacy of raltegravir-based treatment. Rather, raltegravir's twice-daily dosing lead to concerns that imperfect adherence will lead to decreased effectiveness, a concern mitigated through use of a single-tablet regimen such as bictegravir/emtricitabine/tenofovir alafenamide.

HIV Treatment in Pregnancy: The National Core Formulary included dolutegravir, meant to be added to emtricitabine/tenofovir disoproxil fumarate, for treatment of HIV in pregnancy. However, the current guideline from the U.S. Health and Human Services now recommends bictegravir/emtricitabine/tenofovir alafenamide as a first-line agent for treatment in pregnancy as well.[11]

Findings:

After reviewing the guidelines and clinical research discussed above, the NPTC voted to:

a) Remove raltegravir from the National Core Formulary. This had previously been recommended as part of post-exposure prophylaxis.
b) Remove dolutegravir from the National Core Formulary. This had previously been recommended as part of treatment in pregnancy.
c) Remove dolutegravir/abacavir/lamivudine from the National Core Formulary. This had previously been included as a treatment regimen but was not commonly used according to agency pharmacoeconomic trends.

The NPTC retained emtricitabine/tenofovir disoproxil fumarate, for pre-exposure prophylaxis, and bictegravir/emtricitabine/tenofovir alafenamide, which can be used for treatment, including in pregnant patients, as well as for post-exposure prophylaxis.

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.

References:

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