VENTURA COUNTY HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

INTELENCE (Etravirine)

Effective Date: 1/28/14

Date Developed: 1/28/14 by Catherine Sanders, MD

Last Approval Date: 1/26/16, 01/24/17, 1/23/18, 1/22/19, 2/18/20

Intelence is an Antiretroviral Agent, Reverse Transcripase Inhibitor (Non-nucleoside) used in the treatment of HIV-1 infection. Etravirine has activity against HIV-1 by binding to reverse transcriptase. It consequently blocks the RNA-dependent and DNA-dependent DNA polymerase activities, including HIV-1 replication. It does not require intracellular phosphorylation for antiviral activity.

Pre-Authorization Criteria:
Intelence is used in the treatment of HIV-1 infection in combination with at least two additional antiretroviral agents in treatment-experienced patients exhibiting viral replication with documented non-nucleoside reverse transcriptase inhibitor (NNRT) resistance (i.e. resistance to delavirdine, efavirenz or nevirapine).

VCHCP requires that Intelence be prescribed by an Immunology Clinic physician with current American Academy of HIV Medicine (AAHIVM) certification or a physician boarded in Infectious Disease.

Dosing: Adult:
Treatment of HIV-1 infection: Oral: 200 mg twice daily

Dosing: Pediatric:
Treatment of HIV-1 infection: Oral: Children 6 to <18 years:
≥16 kg to <20 kg: 100 mg twice daily
≥20 kg to <25 kg: 125 mg twice daily
≥25 kg to <30 kg: 150 mg twice daily
≥30 kg: 200 mg twice daily

Dosing: Renal Impairment:
No dosage adjustment necessary.
Due to extensive protein binding, significant removal by hemodialysis or peritoneal dialysis is unlikely.

Dosing: Hepatic Impairment:
Mild-to-moderate impairment (Child-Pugh class A or B): No dosage adjustment necessary.
Severe impairment (Child-Pugh class C): No dosage adjustment provided in manufacturer's labeling (has not been studied).

Dosage Forms: U.S.:
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.

Tablet, Oral:
Intelence: 25 mg [scored]
Intelence: 100 mg, 200 mg

Generic Equivalent Available: U.S.-No

Administration:
Administer after meals. If unable to swallow tablets, may disperse tablets in water (≥1 teaspoonful [enough to cover tablets]); stir well (until milky), add additional water (or may add milk or orange juice), and drink immediately. Rinse glass several times (with water, milk or orange juice) and swallow entire contents to ensure administration of dose. Do not use grapefruit juice, carbonated beverages or warm (>40°C) water.

Exclusions:
Intelence is not to be used in treatment-naïve patients, or experienced patients without evidence of viral mutations conferring resistance to NNRTs and PIs.

Adverse Reactions:
>10%: rash, cholesterol (total) increased, hyperglycemia, LDL increased, nausea
Other Serious Less Common Reactions: fat redistribution, immune reconstitution syndrome, skin reactions/hypersensitivity, Stevens-Johnson syndrome, erythema multiforme, toxic epidermal necrolysis, drug rash with eosinophilia and systemic symptoms, hepatotoxicity, autoimmune disorders, MI, atrial fibrillation, angina, pancreatitis, hemolytic anemia, diabetes mellitus, seizures, syncope, acute renal failure, bronchospasm, rhabdomyolysis.

References:

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents, "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents, Department of Health and Human Services," February 12, 2013;1-267. Available at http://www.aidsinfo.nih.gov
2. DHHS Panel on Opportunistic Infections (OI) in HIV-Infected Adults and Adolescents, "Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents: Recommendations from the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the HIV Medicine Association (HIVMA) of the Infectious Diseases Society of America (IDSA)," May 7, 2013. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf
3. Katlama C, Haubrich R, Lalezari J, et al, "Efficacy and Safety of Etravirine in Treatment-Experienced, HIV-1 Patients: Pooled 48 Week Analysis of Two Randomized, Controlled Trials," *AIDS*, 2009, 23(17):2289-300. [PubMed 19710593]
4. Lazzarin A, Campbell T, Clotet B, et al, "Efficacy and Safety of TMC125 (Etravirine) in Treatment-Experienced HIV-1-Infected Patients in DUET-1: 24-Week Results From a Randomised, Double-Blind, Placebo-Controlled Trial," *Lancet,* 2007, 370(9581):39-48. [PubMed 17617271]
5. Madruga JV, Cahn P, Grinsztejn B, et al, "Efficacy and Safety of TMC125 (Etravirine) in Treatment-Experienced HIV-1-Infected Patients in DUET-1: 24-Week Results From a Randomised, Double-Blind, Placebo-Controlled Trial," *Lancet*, 2007, 370(9581):29-38. [PubMed 17617270]
6. www.uptodate.com: Etravirine: Drug Information
7. www.epocrates.com: Intelence Drug Information

REVISION HISTORY:

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