



March 1, 2010

Dear IEHP Provider,

We would like to inform you of the following changes to the 2010/2011 IEHP Formulary that were approved by the Pharmacy and Therapeutics Subcommittee in February 2010:

Drug Name	FDA Approved Indication	Formulary Action-Medi-Cal/HF/HK	Formulary Action-Medicare
Arzerra (ofatumumab)	Oncology	Non-Formulary Criteria: FDA approved indication	Formulary- PA for New Start Only Criteria: FDA approved indication
Berinerit (C1 esterase inhibitor)	Immunological	Non-Formulary Criteria: FDA approved indication	Formulary- PA for New Start Only Use in acute setting only. Criteria: FDA approved indication
Cervarix (HPV Types 16 and 18) vaccine	Vaccine	Formulary Allowed according to the ACIP recommendation	Formulary Allowed according to the ACIP recommendation
Prolastin-c (Alpha-1-Proteinase Inhibitor)	Biologics	Non-Formulary Criteria: FDA approved indication	Non-Formulary Part B Drug Criteria: FDA approved indication
Twynsta (telmisartan/amlodipine)	Cardiac	Non-Formulary Criteria: Use Micardis and Norvasc (generic). Use of Micardis requires failure of first line therapy (ACE inhibitors)	Non-Formulary Criteria: Use Micardis and Norvasc (generic). Use of Micardis requires failure of first line therapy (ACE inhibitors)

Votrient (pazopanib)	Oncology	Non-Formulary Criteria: FDA approved indication	Formulary- PA for New Start Only Criteria: FDA approved indication
Istodax (romidespin)	Oncology	Non-Formulary Criteria: FDA approved indication	Formulary- PA for New Start Only Criteria: FDA approved indication
Lysteda (tranexamic acid)	Hematological	Non-Formulary Criteria: Failure of formulary therapy- Oral contraceptives, progesterone (require documentation of heavy menstrual bleeding)	Non-Formulary Criteria: Failure of formulary therapy- Oral contraceptives, progesterone (require documentation of heavy menstrual bleeding)
Pennsaid Topical solution (diclofenac)	Analgesic	Non-Formulary Criteria: Failure of oral NSAID and topical NSAID- Voltaren Gel	Non-Formulary Criteria: Failure of oral NSAID and topical NSAID- Voltaren Gel
Qutenza (capsaicin) 8% patch	Analgesic	Non-Formulary Criteria: Failure of oral analgesics including NSAID, Ultram, or TCA. Second Line therapies include Cymbalta, Lyrica, Neurontin, Lidocaine; or topical analgesics	Non-Formulary Criteria: Failure of oral analgesics including NSAID, Ultram, or TCA. Second Line therapies include Cymbalta, Lyrica, Neurontin, Lidocaine; or topical analgesics
Revatio (sildenafil)	Pulmonary	Non-Formulary Criteria: FDA approved diagnosis. Other oral PDE-5 inhibitors are allowed.	Non-Formulary Criteria: Oral dosage form is available under Part D. FDA-approved indication.

Kalbitor (ecallantide, DX-88)	Immunological	Non-Formulary Criteria: FDA approved indication	Formulary- PA for New Start Only Use in acute setting only. Criteria: FDA approved indication
Nexcede oral soluble film (12.5mg ketoprofen)	Analgesic	Non-Formulary Criteria: Failure of oral NSAID	Non-Formulary Criteria: Failure of oral NSAID
Zegerid OTC (20mg omeprazole & 1100mg sodium bicarbonate)	GI	Non-Formulary Criteria: Failure of omeprazole (Prilosec OTC), or Prevacid	Non-Formulary Criteria: Failure of omeprazole (or Prilosec OTC), or Prevacid
Wilate (VW factor VIII complex)	Hematological	Non-Formulary Criteria: FDA approved indication.	Non-Formulary Criteria: FDA approved indication.
Vagifem 10mcg (estradiol vaginal tablet)	Hormonal	Non-Formulary Criteria: FDA approved indication. Other estradiol dosage form are available-patch, oral tablet, or vaginal (Estrace)	Non-Formulary Criteria: FDA approved indication. Other estradiol dosage form are available-patch, oral tablet, or vaginal (Estrace)
Zyprexa Relprevv (olanzapine)	Psychiatric	Non-Formulary DHCS Carve out	Formulary- PA for New Start Only Criteria: FDA approved indication. Failure of first line therapy-Risperdal for the treatment of schizophrenia. Available for patients require monthly injection due to compliance issue.
Omeprazole/sodium bicarbonate/mg hydroxide	GI	Non-Formulary Criteria: Failure of omeprazole (Prilosec OTC), or Prevacid	Non-Formulary Criteria: Failure of omeprazole (Prilosec OTC), or Prevacid

Clonidine 24-hour SR tablets and Suspension	Cardiac	Non-Formulary Criteria: Failure of generic clonidine or clonidine TTS patch.	Non-Formulary Criteria: Failure of generic clonidine or clonidine TTS patch.
Lyrica (pregabalin)	Psychiatric	Non-Formulary Criteria: same as Lyrica capsule.	Formulary- PA for New Start Only Criteria: FDA approved indication. Failure of 1 st line therapy TCA, SSRIs, Ultram, Neurontin.
Actemra (tocilizumab)	Rheumatologic	Non-Formulary Criteria: failure of 2 self injectables TNF blockers	Non-Formulary Criteria: failure of 2 self injectables TNF blockers
Ampyra (dalfampridine or 4-aminopyridine)	Immunological	Non-Formulary Criteria: For MS patients who have difficulties walking despite of MS treatment. Compound 4-AP may be considered	Non-Formulary Criteria: For MS patients who have difficulties walking despite of MS treatment. Compound 4-AP may be considered

MODIFICATION OF DRUG CRITERIA			
<i>Drug</i>	<i>Therapeutic Class</i>	<i>Previous Restriction</i>	<i>New Restriction</i>
Synvisc, Euflexxa, Hyalgan (hyaluronate)	Analgesics	<i>Non-Formulary</i>	Non-Formulary If criteria is met: Preferred Product- Euflexxa
Intuniv (guanfacine)	Psychostimulant	<i>Non-Formulary</i>	Non-Formulary Criteria: Diagnosis of ADHD; Tried and failed at least 3 different formulary stimulants. Also required

			to try guanfacine (recommended ½ tab BID then 1 tab BID up to 2mg BID)
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CLINICAL PRACTICE GUIDELINE UPDATE (AVAILABLE AT WWW.IEHP.ORG)		
Clinical Practice Guideline	Therapeutic Class	Comment
Diabetes	Diabetes	The latest guideline developed by the Diabetes Coalition of California and the California Diabetes Program. Please see IEHP website for the complete CPG.
Anti-epilepsy Drug-Brand/Generic Substitution Policy	Anticonvulsant	<p>IEHP allows Brand or Generic form of medications that belongs to the “Narrow Therapeutic Drug” Class (NTD). The newer Anti-epileptic drugs do not require monitoring nor do they belong to the NTD class. Most adverse events due to generic substitution were case reports and no clinical studies demonstrated the adverse events increase with the use of generic anticonvulsants. There is a misunderstanding in regards to the “bioequivalent” standards set by the FDA. Please be reminded that the bioequivalent standard is “90% confidence interval of the mean AUC (area under the time vs concentration curve) and the relative mean Cmax of the test product is within 80% to 125%. It IS NOT referring to 80% to 125% on a mg-by-mg (or dosage) basis.</p> <p>IEHP Policy:</p> <p>New start- generic form must be used unless valid medical justification is provided.</p>

IMPORTANT INFORMATION ABOUT IEHP CLINICAL PRACTICE GUIDELINES

IEHP publishes and distributes an IEHP Formulary Book to our Providers every year. The IEHP Formulary Book contains IEHP treatment guidelines for drug therapy of various medical conditions and policies regarding the use of specific drugs. These recommendations (listed below), which have been approved by the Pharmacy and Therapeutics Subcommittee and Quality Management Committee, are based on published consensus guidelines and reviews of the medical literatures, they do not favor any particular drug based solely on cost considerations. All guidelines for

therapy are current as of the time of printing and are subject to change. The Clinical Practice Guidelines are reviewed at least once every two years, or when a new update is available prior to the two-year schedule. When a new Clinical Practice Guideline is available, IEHP communicates the changes to the Provider via this quarterly Formulary Changes notice. The guidelines are general and may not cover all clinical situations; they should not be considered in any way as a substitute for sound clinical judgment.

IEHP Clinical Practice Guidelines currently available:

- Attention Deficit Hyperactivity Disorder Guideline and Toolkit
- Anti-Infective Therapy Guide Adult and Pediatric
- Asthma
- Depression
- Diabetes Mellitus
- Diabetes Pregnancy
- Fibromyalgia
- Gastroesophageal Reflux Disease
- Hepatitis C
- Hyperlipidemia
- Hypertension
- Migraine
- Multiple Sclerosis
- Pain Management
- Pulmonary Arterial Hypertension
- Respiratory Syncytial Virus
- Rheumatoid Arthritis
- Sexually Transmitted Diseases - Summary of CDC Treatment Guidelines
- Smoking Cessation
- Synagis Criteria Season 2009/2010

We welcome any recommendations and comments regarding the IEHP Formulary. For questions, suggestions, or if you would like a printed copy of the IEHP Formulary Book or Clinical Practice Guideline, please call us at (909) 890-2067. As a reminder, updated formulary information and Clinical Practice Guidelines are available at www.iehp.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Chris Chan', written in a cursive style.

Chris Chan, Pharm.D.

Director of Pharmaceutical Services