

**Indiana Hoosier Healthwise
PDL Changes
June 2009 DUR Board Presentation**

Additions to PDL with NO Clinical Edits

Terbinafine cream (OTC)

Additions to PDL with Clinical Edits

Product	Edit
Dexamphetamine/amphetamine ER (generic form of Adderall XR)	Subject to the same Mental Health Quality Assurance Committee edits for dose optimization as Adderall XR: QL: 5, 10, 15 mg = 1/day; 20, 25, 30mg = 2/day
RENVELA, FOSRENOL	<p>PA: To encourage the use of first line or preferred medications when appropriate</p> <p>Requests for Renvela or Fosrenol may be approved for members who meet the following criteria:</p> <ul style="list-style-type: none"> I. Diagnosis must be Hyperphosphatemia with end stage renal disease (ESRD); AND II. Patient must be on dialysis; AND III. Current phosphorus level should be > 5.5 mg/dL; AND IV. If Ca levels are low or within normal limits, member must have tried PhosLo (verified by paid claims)
AVONEX, BETASERON, REBIF	<p>PA: To encourage appropriate use based on FDA approved or medically accepted indications.</p> <p>Requests may be approved for members who meet the following criteria:</p> <ul style="list-style-type: none"> I. Member with a single demyelinating episode with consistent MRI findings, considered at high risk for clinically definite MS; OR II. Member with relapsing-remitting multiple sclerosis (RRMS); OR III. Member with secondary progressive multiple sclerosis (SPMS) with a history of superimposed relapses.
COPAXONE	<p>PA: To encourage appropriate use based on FDA approved or medically accepted indications</p> <p>Requests may be approved for members who meet the following criteria:</p> <ul style="list-style-type: none"> I. Member has relapsing-remitting multiple sclerosis (RRMS).
TYSABRI	PA: To encourage appropriate use based on FDA

	<p>approved or medically accepted indications.</p> <p>Requests for Tysabri (natalizumab) may be approved for members who meet the following criteria:</p> <p>I. Member has a diagnosis of relapsing forms of Multiple Sclerosis (MS) and meets all of the following:</p> <ul style="list-style-type: none"> A. Member is 18 years of age or older, AND B. Member has had a gadolinium – enhanced MRI scan of the brain and, when indicated, cerebrospinal fluid analysis to help differentiate potential future MS symptoms from PML as required by the FDA AND C. Member has had an inadequate response to, or is unable to tolerate, alternative treatments for MS (e.g. Beta Interferons [Avonex, Rebif], interferon beta 1-b [Betaseron], glatiramer Acetate [Copaxone]), AND D. Tysabri will be used as monotherapy, AND E. Member is not currently on other immune system modifying drugs such as antineoplastics, immunosuppressants or immunomodulators, AND F. Member does not have a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, or lymphoma or organ transplantation, AND G. Member does not have current or prior history of progressive multifocal leukoencephalopathy (PML), AND H. Member has enrolled in and met all conditions of the MS TOUCH (Multiple Sclerosis Tysabri Outreach: Unified Commitment to Health) Prescribing Program. <p>OR</p> <p>II. Member has a diagnosis of moderate to severe active Crohn’s disease with evidence of inflammation and meets all of the following:</p> <ul style="list-style-type: none"> A. Member is 18 years of age or older, AND B. Member has had an inadequate response or is unable to tolerate conventional therapies (e.g. sulfasalazine, mesalamine products, corticosteroids, immunosuppressants [6-mercaptopurine, azathioprine, cyclosporine, or methotrexate]) AND C. Member has had an inadequate response or is unable to tolerate Remicade
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	<p>AND Humira, AND</p> <p>D. Tysabri is not used concomitantly with immunosuppressants (6-mercaptopurine, azathioprine, cyclosporine, or methotrexate), or tumor necrosis factor antagonists, AND</p> <p>E. Member does not have a medical condition which significantly compromises the immune system including HIV infection or AIDS, leukemia, or lymphoma or organ transplantation, AND</p> <p>F. If the member is on chronic oral corticosteroids, steroid tapering should begin as soon as a therapeutic benefit of Tysabri has occurred, AND</p> <p>G. If oral corticosteroids cannot be tapered within six months of starting therapy, Tysabri must be discontinued, AND</p> <p>H. If the member has not experienced therapeutic benefit by 12 weeks of induction therapy, Tysabri must be discontinued, AND</p> <p>I. Member does not have current or prior history of progressive multifocal leukoencephalopathy (PML), AND</p> <p>J. Member is enrolled in and meets all conditions of the CD TOUCH® (Crohn's Disease Tysabri Outreach: Unified Commitment to Health) Prescribing Program</p> <p>Prescribers should determine every six months whether individuals should continue on treatment.</p> <p>NOTE: The safety and efficacy of Tysabri® beyond two years is unknown. Additionally, Tysabri® has not been studied in those 65 years or older and patients with renal or hepatic insufficiency.</p>
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Removal of Clinical Edits from Existing PDL products

NA

Addition of Clinical Edits to Existing PDL products

Product	Edit
ALDARA	<p>QL: To encourage appropriate use based on FDA approved or medically accepted indications.</p> <p>Requests for higher quantities of Aldara (imiquimod) may be approved for members who meet the following criteria:</p> <ul style="list-style-type: none"> I. For diagnosis of Actinic Keratosis or External Genital Warts, may approve 12 packets per 30 days for up to 16 weeks; OR II. For diagnosis of Superficial Basal Cell

	<p>Carcinoma, Non-melanoma skin cancer or Molluscum contagiosum, may approve 36 packets per 30 days for up to 6 weeks</p> <p>Requests for higher quantity will be reviewed on a case by case basis. Higher quantities may be approved if the member is being treated by a dermatologist.</p>
<p>ALENDRONATE, EVISTA</p>	<p>AGE: To encourage appropriate use based on FDA approved indications and clinical guidelines for certain age groups</p> <p>Requests for Bisphosphonates may be approved for members who meet the following criteria:</p> <ul style="list-style-type: none"> I. Member is <u>female and is 50 years of age or older</u>; OR II. Member is <u>female and less than 50 years of age</u> and meets the following criteria: <ul style="list-style-type: none"> a. Low bone mineral density below the expected range for age (Z-score \leq -2.0); AND b. Early natural menopause; OR c. Surgically induced menopause; OR III. Member is <u>male</u> with one of the following: <ul style="list-style-type: none"> a. Low bone mass with T-score between -1.0 and -2.5 at the femoral neck or spine with a 10-year probability of a hip or major osteoporotic-related fracture b. T-score \leq -2.5 at the femoral neck or spine after appropriate evaluation to exclude secondary causes c. A hip or vertebral (clinical or morphometric) fracture; OR <p>Member has a diagnosis of Paget's Disease</p>
<p>Ciprofloxacin ER (preferred products available – ciprofloxacin, ofloxacin,) Ciclopirox (preferred products available – clotrimazole, econazole, ketoconazole, miconazole, nystatin, tolnaftate) Cimetidine (preferred products available – ranitidine, famotidine) Etodolac CR (preferred products available – diclofenac, flurbiprofen, ibuprofen, indomethacin, meloxicam, nabumetone, naproxen, oxaprozin,</p>	<p>PA: To encourage the use of first line or preferred medications when appropriate. Requests for the above selected generic products may be approved for members who meet the following criteria:</p> <p>Member has been unable to achieve efficacy with two preferred generic products of lower cost</p> <p>FDA Approved Indications: Ciprofloxacin ER: For the treatment of UTIs,</p>

<p>piroxicam, sulindac) Halobetasol (preferred products available – betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide, fluticasone, hydrocortisone, triamcinolone) Ketoprofen, Ketoprofen CR (preferred products available – diclofenac, flurbiprofen, ibuprofen, indomethacin, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac) Mometasone Furoate (preferred products available –betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide, fluticasone, hydrocortisone, triamcinolone) Nabumetone (preferred products available – diclofenac, flurbiprofen, ibuprofen, indomethacin, meloxicam, nabumetone, naproxen, oxaprozin, piroxicam, sulindac) Nizatadine (preferred products available – ranitidine, famotidine) Orphenadrine (preferred products available – baclofen, carisoprodol, chlorzoxazone, cyclobenzaorine, dantrolene, methorcarbamol, tizanidine) Prednicarbate (preferred products available – betamethasone, clobetasol, desonide, desoximetasone, diflorasone, fluocinolone, fluocinonide, fluticasone, hydrocortisone, triamcinolone)</p>	<p>including acute uncomplicated pyelonephritis, caused by susceptible strains of the designated microorganisms in the following list. The safety and efficacy of ciprofloxacin ER in treating infections other than UTIs have not been demonstrated. Ciclopirox: For the topical treatment of the following dermal infections: tinea pedis, tinea cruris, and tinea corporis due to <i>Trichophyton rubrum</i>, <i>T. mentagrophytes</i>, <i>Epidermophyton floccosum</i>, and <i>Microsporum canis</i>; cutaneous candidiasis (moniliasis) due to <i>Candida albicans</i>; and tinea (pityriasis) versicolor due to <i>Malassezia furfur</i>. Cimetidine: Benign gastric ulcer: For short-term treatment of active, benign gastric ulcer. Duodenal ulcer: For short-term treatment of active duodenal ulcer and maintenance therapy after the healing of active ulcer. Gastroesophageal reflux disease (GERD), erosive: For the treatment of erosive esophagitis diagnosed by endoscopy. Pathological hypersecretory conditions: For the treatment of pathological hypersecretory conditions (eg, Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas). Heartburn (OTC only): For the relief of heartburn associated with acid indigestion and sour stomach; for the prevention of heartburn associated with acid indigestion and sour stomach brought on by certain foods and beverages. Etodolac CR: For the relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and juvenile rheumatoid arthritis; for the management of other types of pain. Halobetasol: Super-high potency corticosteroids for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g/week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Ketoprofen: For the management of the signs and symptoms of rheumatoid arthritis and osteoarthritis. Mometasone Furoate: A medium potency corticosteroid for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Nabumetone: For acute and chronic treatment of signs and symptoms of osteoarthritis (OA) and rheumatoid arthritis (RA). Nizatadine: Benign gastric ulcer: For the treatment of active benign ulcer for up to 8 weeks. Duodenal ulcer: For the treatment of active ulcer for up to 8 weeks and maintenance therapy after healing of active ulcer. Gastroesophageal reflux disease (GERD): For the treatment of endoscopically diagnosed esophagitis, including erosive and</p>
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	<p>ulcerative esophagitis, and associated heartburn due to GERD for up to 12 weeks in adults and up to 8 weeks in children (12 years of age and older).^{1,2}</p> <p>Heartburn (OTC product only): For the relief of heartburn, acid indigestion, and sour stomach and the prevention of these symptoms brought on by certain foods and beverages.</p> <p>Orphenadrine: As an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculoskeletal conditions.</p> <p>Prednicarbate: A medium-potency corticosteroid for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.</p>
<p>DRONABINOL</p>	<p>PA: To encourage appropriate use based on FDA approved or medically accepted indications.</p> <p>Requests for Marinol (dronabinol) may be approved for members who meet the following criteria:</p> <ol style="list-style-type: none"> I. Member has diagnosis of AIDS and medication is being used for appetite stimulation II. Member is using for chemotherapy-induced nausea and vomiting prophylaxis and has tried two of the following medications: <ol style="list-style-type: none"> a. promethazine (Phenergan) b. prochlorperazine (Compazine) c. metoclopramide (Reglan) d. ondansetron (Zofran) e. granisetron (Kytril) f. dexamethasone <p>Dronabinol (Marinol), a cannabinoid, is considered a lower therapeutic index drug in preventing cancer chemotherapy related emesis. Lower therapeutic index drugs should not be used as first line agents. They may be used for patients of high or moderate emetic risk if they are intolerant or refractory to the 5-HT₃ serotonin receptor antagonists, dexamethasone, and aprepitant. The guidelines reflect the FDA approved use of dronabinol (Marinol) for use in patients with nausea and vomiting due to chemotherapy who have failed conventional therapies.</p>
<p>XENAZINE</p>	<p>PA: To encourage appropriate use based on FDA approved or medically accepted indications.</p> <p>Requests for Xenazine (tetrabenazine) may be approved for members who meet the following criteria:</p> <p>Member has a diagnosis of chorea associated with Huntington's Disease.</p>

KETOROLAC	<p>QL: To encourage appropriate use based on FDA approved dosage guidelines</p> <p>Requests for ketorolac (Toradol) may be approved if the member meets the following criteria:</p> <ul style="list-style-type: none"> ➤ Diagnosis of short term use for post operative pain not to exceed duration of 5 days of therapy (20 tablets per 30 days). <p>Quantity limit is based on potential for severe toxicity. Switch members to alternative analgesics as soon as possible.</p> <p>If an increase in the quantity limit of ketorolac (Toradol) and one of the criteria is not met, request will be reviewed on a case by case basis. Cases will be sent to Utilization Management for review.</p>
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Change to Non-Preferred

Product	Rationale	Alternative
RENAGEL	Comparable safety and efficacy to other available phosphate binders	PDL available alternatives include Phos-LO, RENVELA, FOSRENOL ** growth hormone requires PA

