Commissioner for the Department for Medicaid Services
Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for the Department for Medicaid Services based on the September 18, 2014 Pharmacy and Therapeutics (P&T) Advisory Committee Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: Adempas® Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension; however, approve riociguat (Adempas®) if the following are true: • Diagnosis of PAH (WHO Group I) after trial and failure of two preferred products; OR • Diagnosis of CTEPH (WHO Group 4) functional class II or III deemed inoperable or with residual PH after undergoing pulmonary endarterectomy.	The final PDL placement will be determined after a re-review of this product at the next P&T meeting.
New Products to Market: Orenitram™ Place this product non preferred in the PDL class titled Agents for Pulmonary Hypertension.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Zontivity™ Place this product non preferred in the PDL class titled Platelet Inhibitors; however, approve Zontivity™ for a diagnosis of history of myocardial infarction (MI) or peripheral artery disease (PAD) WITHOUT a history of stroke, transient ischemic attack (TIA), acute coronary syndrome (ACS), gastrointestinal (GI) bleed, or peptic ulcer. Patients must also be taking aspirin and/or clopidogrel concomitantly.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Velphoro® Place this product non preferred in the PDL class titled Phosphate Binders.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Tanzeum™ Place this product non preferred in the PDL class titled GLP-1 Receptor Agonists.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Otezla® Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Immunomodulators.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Entyvio™ Place this product non preferred with appropriate quantity limits and similar approval criteria in the PDL class titled Immunomodulators.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Zykadia™ Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology Agents.	The final PDL placement will be determined after a review of this product at the next P&T meeting.

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New Products to Market: Zohydro ER™ Place this product non preferred with appropriate quantity limits in the PDL class titled Narcotics: Long-Acting.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Evzio™ Evzio™ will be limited to 4 auto injectors per prescription and will only be approved in the following circumstances: ▪ Patient or care-giver is administering medication outside of a healthcare facility (such as a personal residence or school); AND ▪ Patient or active care-giver is unable to manipulate vials/syringes due to issues related to poor eyesight, dexterity, or comprehension; AND ▪ The prescriber has completed and submitted with the prior approval request the Opioid Overdose Risk Assessment Checklist Form. The form can be found at: http://evzio.com/pdfs/Evzio-Opioid-Overdose-Risk-Assessment-Checklist.pdf; AND ▪ If the diagnosis is substance abuse, dependence and/or addition, the patient is receiving addiction counseling services; such as psychosocial therapy from a Substance Abuse provider. Documentation must be provided to include provider name, type of provider, and provider phone number.	The final criteria will be determined after a review of this product at the next P&T meeting.
New Products to Market: Aptiom® Place this product non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Hetlioz® Place this product non preferred with appropriate quantity limits in the PDL class titled Sedative Hypnotics; however, only approve tasimelteon (Hetlioz®) for a diagnosis of Non-24-hour sleep-wake disorder ("non-24") in patients who are totally blind.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Anoro™ Ellipta™ Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents; however, approve Anoro™ Ellipta™ for a diagnosis of COPD after trial and failure of an inhaled long-acting bronchodilator (a LABA or an anticholinergic).	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Sivextro™ Place this product non preferred with appropriate quantity limits and similar criteria in the PDL class titled Oxazolidinones.	The final PDL placement will be determined after a review of this product at the next P&T meeting.

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New Products to Market: Luzu® Place this product non preferred in the PDL class titled Topical Antifungal Agents.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Jublia® Place this product non preferred in the PDL class titled Topical Antifungal Agents; however, only approve efinaconazole (Jublia®) for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
Topical Antifungal Agents 1. DMS to select preferred agent(s) based on economic evaluation; however, at least agents representing multiple mechanisms of action as well as a combination product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis. 4. For any new chemical entity in the Topical Antifungal Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** clotrimazole solution, cream econazole ketoconazole shampoo, cream nystatin cream, ointment, powder nystatin/triamcinolone cream, ointment **Non Preferred Agent (s)** Bensal HP® Ciclodan® cream/kit Ciclodan™ solution ciclopirox clotrimazole /betamethasone CNL-8™ Ecoza™ Ertaczo® Exelderm® Extina® ketoconazole foam Ketodan™ Loprox® Lotrimin® Lotrisone® Mentax® Naftin® Nizoral Shampoo® Oxistat® Pediaderm AF® Pedipirox-4™ Penlac® Vusion® Xolegel®

Description of Recommendation	Final Decision (s)
Topical Antiviral Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Antiviral Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** acyclovir ointment **Non Preferred Agent (s)** Denavir® Xerese™ Zovirax® cream Zovirax® ointment
Topical Antibiotic Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be mupirocin ointment, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Antibiotic Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Bactroban® cream gentamicin 0.1% cream, ointment mupirocin ointment neomycin/polymyxin/pramoxine **Non Preferred Agent (s)** Altabax™ Bactroban® ointment Centany® mupirocin cream Triple Antibiotic®
Topical Antiparasitic Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities, one of which should be permethrin 5% cream, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Topical Antiparasitic Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Eurax® Natroba® permethrin 5% cream Sklice® **Non Preferred Agent (s)** Elimite™ lindane malathion Ovide® spinosad Ulesfia®

Description of Recommendation	Final Decision (s)
Topical Psoriasis Agents 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Topical Psoriasis Agents, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** calcipotriene salicylic acid shampoo, gel urea cream **Non Preferred Agent (s)** Aluvea® Bensal HP® BP 50% calcipotriene/betamethasone Calcitrene™ calcitriol ointment Cem-Urea® Dovonex® Latrix® Latrix XM® Remeven® Salacyn® lotion, cream salicylic acid cream, lotion, 26% liquid27.5% liquid, combo pkg, kit Salex® shampoo, combo pkg, kit Sorilux™ Taclonex® ointment, suspension Taclonex® Scalp Tazorac® Umecta® Kit, foam, emulsion, suspension Umecta® PD suspension, emulsion Uramaxin® Uramaxin® GT urea suspension, gel, lotion, nail film suspension, kit, foam, emulsion Vectical™ X-Viate®
Oral Psoriasis Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any new chemical entity in the Oral Psoriasis Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Oxsoralean-Ultra® Soriatane® **Non Preferred Agent (s)** 8-MOP® acitretin methoxsalen

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Oral Acne Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any new chemical entity in the Oral Acne Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Amnesteem® Claravis™ Myorisan™ Sotret® Zenatane™ **Non Preferred Agent (s)** Absorica™
Otic Antibiotics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single entity otic quinolone, one otic quinolone/steroid combination product and one non-quinolone combination product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Otic Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Ciprodex® Otic hydrocortisone 1%/neomycin sulfate 5 mg/polymyxin B 10,000 units solution and suspension ofloxacin 0.3% solution **Non Preferred Agent (s)** Cetraxal® ciprofloxacin 0.2% Cipro HC® Otic Coly-mycin® S Cortisporin® solution Cortisporin®-TC Floxin® Otic

Description of Recommendation	Final Decision (s)
Otic Anti-Infective/Anesthetics/Anti-Inflammatories 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Otic Anti-Infective/Anesthetics/Anti-Inflammatories class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** acetic acid antipyrine/benzocaine **Non Preferred Agent (s)** Acetasol HC® acetic acid/hydrocortisone acetic acid in aluminum acetate Aralagan® Aurodex® Auroguard® chloroxylenol/pramoxine/hydrocortisone Dermotic® Dolotic® fluocinolone 0.01% oil Myoxin® Neotic® Otic Care® Oto-End 10® Otozin™ Pinnacaine® Pramotic® Pramoxine HC® PR Otic® Trioxin® Vosol® Vosol® HC
Alpha Blockers for BPH 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two agents, one of which should be highly selective for the alpha receptors in the genitourinary tract, should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Alpha Blockers for BPH class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** alfuzosin ER doxazosin tamsulosin terazosin **Non Preferred Agent (s)** Cardura® Cardura XL® Flomax® Hytrin® Rapaflo™ Uroxatral®

Description of Recommendation	Final Decision (s)
5-Alpha Reductase (5AR) Inhibitors 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one single-entity agent should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the 5-Alpha Reductase Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** finasteride **Non Preferred Agent (s)** Avodart® Jalyn® Proscar®
5-Alpha Reductase (5AR) Inhibitors Clinical Criteria 5-Alpha Reductase (5AR) Inhibitors will be approved for a diagnosis of benign prostatic hyperplasia (BPH) via an ICD-9 override.	5-Alpha Reductase (5AR) Inhibitors will be approved for a diagnosis of benign prostatic hyperplasia (BPH) via an ICD-9 override.
Tadalafil (Cialis®) Clinical Criteria Tadalafil (Cialis®) will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both: • An alpha blocker for one month; AND • A 5-Alpha Reductase Inhibitor for four months. Cialis® should not be used in combination with an alpha blocker.	Tadalafil (Cialis®) will be approved for a diagnosis of benign prostatic hyperplasia (BPH) after trial and failure of both: • An alpha blocker for one month; AND • A 5-Alpha Reductase Inhibitor for four months. Cialis® should not be used in combination with an alpha blocker.
Bladder Relaxants 1. DMS to select preferred agent (s) based on economic evaluation; however, at least three unique chemical entities should be preferred. 2. Only patients who are unable to swallow or tolerate oral medications should be approved for non-oral formulations of agents in this class. 3. Continue current quantity limits on all agents in this class. 4. Agents not selected as preferred will be considered non preferred and require PA. 5. For any new chemical entity in the Bladder Relaxants Class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** oxybutynin Toviaz™ VESIcare® **Non Preferred Agent (s)** Detrol® Detrol® LA Ditropan® XL Enablex® flavoxate Gelnique™ Myrbetriq™ oxybutynin ER Oxytrol® Sanctura® Sanctura® XR tolterodine tolterodine ER trospium trospium ER

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Oral Oncology Agents 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a first-line recommendation by the NCCN for each cancer type should be preferred. Due to new data on the treatment of CML, both imatinib and EITHER dasatinib OR nilotinib should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose. 3. Agents not selected as preferred will be considered non preferred and require PA. 4. DMS to allow continuation of therapy for existing users of non preferred single-source branded products via a 90 day look back. 5. For any new chemical entity in the Oral Oncology Agents class, require a PA until reviewed by the P&T Advisory Committee.	The final PDL placement will be determined after a review of this class at the next P&T meeting.
Vaginal Antibiotics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least metronidazole should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Vaginal Antibiotics class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Cleocin® Ovules metronidazole vaginal 0.75% gel **Non Preferred Agent (s)** Cleocin® cream clindamycin vaginal 2% cream Clindesse® Metrogel Vaginal® Vandazole®
Irritable Bowel Syndrome 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Irritable Bowel Syndrome class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** Amitiza® Linzess® **Non Preferred Agent (s)** Lotronex®

Description of Recommendation	Final Decision (s)
Irritable Bowel Syndrome Clinical Criteria Agents will be approved for the following diagnoses: • Irritable Bowel Syndrome with constipation (linaclotide and lubiprostone) or with diarrhea (alosetron); OR • Chronic Idiopathic Constipation after failure of one laxative (linaclotide and lubiprostone); OR • Opioid-Induced Constipation (lubiprostone) if the following are true: o Patient is experiencing chronic, non-cancer pain; and o Patient has tried and failed one laxative.	Agents will be approved for the following diagnoses: • Irritable Bowel Syndrome with constipation (linaclotide and lubiprostone) or with diarrhea (alosetron); OR • Chronic Idiopathic Constipation after failure of one laxative (linaclotide and lubiprostone); OR • Opioid-Induced Constipation (lubiprostone) if the following are true: o Patient is experiencing chronic, non-cancer pain; and o Patient has tried and failed one laxative.
Topical Rosacea Agents 1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred. 2. Agents not selected as preferred will be considered non preferred and require prior authorization. 3. For any new chemical entity in the Topical Rosacea Agents class, require a PA until reviewed by the P&T Advisory Committee.	**Selected Preferred Agent (s)** metronidazole lotion, cream, gel **Non Preferred Agent (s)** Azelex® Finacea® Finacea® Plus MetroCream® MetroGel® MetroGel® Kit MetroLotion® Mirvaso® Noritate® Rosadan® Kit

Description of Recommendation	Final Decision (s)
Palivizumab (Synagis®) Clinical Criteria **Length of authorization:** • Authorization will be granted for a maximum of 5 doses during RSV reason (five monthly doses of 15 mg/kg IM). Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed. • For infants and children < 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO). **Approval Criteria:** Palivizumab will be approved in the following scenarios:	**Length of authorization:** • Authorization will be granted for a maximum of 5 doses during RSV reason (five monthly doses of 15 mg/kg IM). Despite differences in onset and offset of RSV infection in some states or regions, only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed. • For infants and children < 24 months of age, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO). **Approval Criteria:** Palivizumab will be approved in the following scenarios:

Infant/Child Age at Start of RSV Season	Criteria
<12 months (1^{st} year of life)	▪ GA <29 wks, 0 d (otherwise healthy); or ▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth); or ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions; or ▪ Profoundly immunocompromised; or ▪ CF with CLD and/or nutritional compromise
≤ 12 months (1^{st} year of life)	▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist
>12 months (2^{nd} year of life)	▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2^{nd} RSV season; or ▪ CF with severe lung disease* or weight for length <10^{th} percentile
<24 months (2^{nd} year of life)	▪ Cardiac transplant during RSV season; or ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO; or ▪ Profoundly immunocompromised during the RSV season

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O_2=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation

*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1^{st} year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

Infant/Child Age at Start of RSV Season	Criteria
<12 months (1^{st} year of life)	▪ GA <29 wks, 0 d (otherwise healthy); or ▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth); or ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions; or ▪ Profoundly immunocompromised; or ▪ CF with CLD and/or nutritional compromise
≤ 12 months (1^{st} year of life)	▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist
>12 months (2^{nd} year of life)	▪ CLD of prematurity (GA <32 wks, 0 d and >21% O_2 x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2^{nd} RSV season; or ▪ CF with severe lung disease* or weight for length <10^{th} percentile
<24 months (2^{nd} year of life)	▪ Cardiac transplant during RSV season; or ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO; or ▪ Profoundly immunocompromised during the RSV season

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O_2=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation

*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1^{st} year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

Description of Recommendation	Final Decision (s)
Botulinum Toxins Clinical Criteria AbobotulinumtoxinA (Dysport™) OR rimabotulinumtoxinB (Myobloc®) will be approved for a diagnosis of cervical dystonia. IncobotulinumtoxinA (Xeomin®) will be approved for the following diagnoses: • Cervical dystonia; OR • Blepharospasm after trial and failure of onabotulinumtoxinA (Botox®). OnabotulinumtoxinA (Botox®) will be approved for the following diagnoses: • Blepharospasm ; OR • Cervical dystonia; OR • Severe primary axillary hyperhidrosis ; OR • Strabismus; OR • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants; or o Bracing; or o Splinting; or o Occupational therapy; or o Physical therapy; OR • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least two (2) of the following: ▪ Beta-blocker; or ▪ Amitriptyline; or ▪ Valproate; or ▪ Topiramate; AND o Tried and failed abortive therapy with two triptans; OR • Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication; OR • Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency after trial and failure of or contraindication to an anticholinergic medication.	AbobotulinumtoxinA (Dysport™) OR rimabotulinumtoxinB (Myobloc®) will be approved for a diagnosis of cervical dystonia. IncobotulinumtoxinA (Xeomin®) will be approved for the following diagnoses: • Cervical dystonia; OR • Blepharospasm after trial and failure of onabotulinumtoxinA (Botox®). OnabotulinumtoxinA (Botox®) will be approved for the following diagnoses: • Blepharospasm ; OR • Cervical dystonia; OR • Severe primary axillary hyperhidrosis ; OR • Strabismus; OR • Cerebral Palsy or other spasticity disorders as long as patient has tried ONE other option such as: o Muscle relaxants; or o Bracing; or o Splinting; or o Occupational therapy; or o Physical therapy; OR • Chronic migraines after trial and failure of ALL of the following (unless contraindication or intolerance): o Prophylactic therapy with at least two (2) of the following: ▪ Beta-blocker; or ▪ Amitriptyline; or ▪ Valproate; or ▪ Topiramate; AND o Tried and failed abortive therapy with two triptans; OR • Urinary incontinence due to detrusor overactivity associated with a neurologic condition (such as spinal cord injury or MS) after trial and failure of or contraindication to an anticholinergic medication; OR • Overactive bladder with symptoms of urge urinary incontinence, urgency and frequency after trial and failure of or contraindication to an anticholinergic medication.

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Clonidine Patch Clinical Criteria Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Patient cannot tolerate/absorb PO.	Clonidine patches will be approved if any one of the following is true: • Patient is <15 years old; OR • Patient cannot tolerate/absorb PO.
Phenoxybenzamine (Dibenzyline®) Phenoxybenzamine (Dibenzyline®) will be approved for a diagnosis of Pheochromocytoma only.	Phenoxybenzamine (Dibenzyline®) will be approved for a diagnosis of Pheochromocytoma only.
Lidocaine Patch (Lidoderm®) Clinical Criteria Lidocaine patches (Lidoderm®) will be approved if any one of the following criteria is met: • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • Diagnosis of neuropathic pain and history of one agent in any of the following medication classes in the past 90 days: o Tricyclic antidepressant; or o Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); or o SNRI.	Lidocaine patches (Lidoderm®) will be approved if any one of the following criteria is met: • Diagnosis of Post Herpetic Neuralgia via an ICD-9 override; OR • Diagnosis of neuropathic pain and history of one agent in any of the following medication classes in the past 90 days: o Tricyclic antidepressant; or o Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); or o SNRI.
Capsaicin Patch (Qutenza®) Clinical Criteria Capsaicin Patch (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • Tricyclic antidepressant; OR • Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); OR • SNRI.	Capsaicin Patch (Qutenza®) will be approved for a diagnosis of postherpetic neuralgia after trial and failure of one of the following agents: • Tricyclic antidepressant; OR • Anticonvulsant used for neuropathic pain (i.e. gabapentin, pregabalin); OR • SNRI.
Prenatal Vitamins Clinical Criteria Prenatal vitamins will be approved if one of the following is true: • Patient is female and currently pregnant; OR • Patient is female and actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.	Prenatal vitamins will be approved if one of the following is true: • Patient is female and currently pregnant; OR • Patient is female and actively nursing; OR • Patient suffers from a chronic condition associated with wasting (i.e., HIV) or malabsorption.
Becaplermin (Regranex®) Clinical Criteria Becaplermin (Regranex®) will be approved for a diagnosis of lower extremity diabetic neuropathic ulcers.	Becaplermin (Regranex®) will be approved for a diagnosis of lower extremity diabetic neuropathic ulcers.
Peginterferon Alfa 2b (Sylatron™) Clinical Criteria Peginterferon Alfa 2b (Sylatron™) will be approved for a diagnosis of melanoma only.	Peginterferon Alfa 2b (Sylatron™) will be approved for a diagnosis of melanoma only.

Description of Recommendation	Final Decision (s)

Omalizumab (Xolair®) Clinical Criteria
Initial Therapy (6 months):
Xolair® (omalizumab) will be approved for the following diagnoses:
• Moderate to severe asthma (step 5 or higher) if ALL of the following are true:
  o 12 years of age or older; AND
  o Positive skin test or in vitro reactivity to a perennial aeroallergen; AND
  o FEV1 of <80% while on asthma controller medication; AND
  o Has had failure of or contraindication to inhaled corticosteroid in combination with a second controller agent (such as a long-acting inhaled beta2-agonist, ipratropium, leukotriene modifier, or theophylline) for a 60-day trial.
• Chronic idiopathic urticaria if ALL of the following are true:
  o 12 years of age or older; AND
  o The underlying cause of the patient's condition has been ruled out and is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; AND
  o Documented baseline urticaria activity score (UAS7), renewals will require submission of current UAS7 (within previous 30 days); AND
  o One of the following:
  ▪ 3-month trial and failure of two (2) H1 antihistamines at maximally tolerated doses and patient has documented ongoing symptoms of chronic idiopathic urticaria; or
  ▪ 3-month trial and failure of one antihistamine products and one (1) of the following leukotriene antagonists: Singulair (montelukast) OR Accolate (zafirlukast) and patient has documented ongoing symptoms of chronic idiopathic urticaria.
 	
Continuation of Therapy:
Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses:
• Moderate to severe asthma (step 5 or higher) if one
	The final criteria will be determined after a review of this product at the next P&T meeting.

of the following is true: ○ During previous treatment with Xolair®, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre-Xolair® baseline, OR ○ The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their oral corticosteroid dose to less than their pre-Xolair® baseline or to ≤ 5 mg daily, OR ○ The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of Xolair® and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-Xolair® baseline. • Chronic idiopathic urticaria if ALL of the following are true: ○ Treatment with Xolair® (omalizumab) has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; AND ○ Submitted current UAS7 was recorded within the past 30 days.	