

## Prior Authorization/Step Therapy Program

This program encourages safe, cost-effective medication use by allowing coverage when certain conditions are met. A clinical team of physicians and pharmacists develops and approves the clinical programs and criteria by reviewing FDA-approved labeling, scientific literature and nationally recognized guidelines.

| Prior Authorization             |  |  |  |
|---------------------------------|--|--|--|
| Drug Category                   | Target Drugs   | Program Intent   |  |
| Androgens/<br>Anabolic Steroids | Anadrol-50, Androderm, Androgel,<br>Android, Androxy, Aveed, Axiron,<br>danazol, Delatestryl, Depo-Testosterone,<br>First-Testosterone, Fortesta, Methitest,<br>Oxandrin, Striant, Testim, Testred, Vogelxo            | Helps ensure that patients are appropriately selected and treated according to<br>parameters defined in product labeling, clinical evidence and/or clinical guidelines.<br>Upon meeting criteria, use of one of the formulary topical agents, Androderm or<br>Androgel, is typically required before non-formulary topical products. A quantity<br>limit is applied to all topical testosterone products. Both brand and generic agents<br>are targeted. |  |
| Antifungal Agents               | Noxafil, Vfend   | Helps ensure appropriate selection of patients for treatment when prescribed for indications approved in product labeling. Both brand and generic agents are targeted.   |  |
| Doxycycline/<br>Minocycline     | <i>Doxycycline products</i> : Acticlate, Adoxa,<br>Alodox, Avidoxy DK, Doryx (and generic<br>equivalents), doxycycline, Monodox,<br>Morgidox Kit, Nicazeldoxy, Nutridox Kit,<br>Ocudox Kit, Oracea, Oraxyl, Vibramycin | Helps ensure appropriate selection of patients for treatment according to product labeling, clinical studies and/or clinical guidelines and encourages use of first-line generic agents and topical acne products before use of targeted products, when  |  |
|                                 | <i>Minocycline products</i> : Dynacin, Minocin,<br>Minocin Kit, Solodyn (and generic<br>equivalents)   | appropriate.   |  |
| Erectile Dysfunction            | Caverject, Cialis, Edex, Levitra, Muse,<br>Staxyn, Stendra, Viagra   | Helps ensure appropriate selection of patients for therapy according to product<br>labeling, clinical guidelines and/or clinical studies. If prescribed for benign<br>prostatic hyperplasia (BPH), encourages the use of a generic alpha blocker prior to<br>consideration of Cialis at the recommended FDA-approved dose. A quantity limit is<br>applied to these agents.   |  |
| Fentanyl (Oral/Nasal)           | Abstral, Actiq, Fentora, Lazanda, Onsolis,<br>Subsys   | Encourages appropriate use for the treatment of breakthrough pain in cancer patients who are opioid-tolerant. A quantity limit is applied to these agents. Both brand and generic agents are targeted.   |  |
| Insulin Agents                  | Apidra, Humalog, Humalog Mix 75/25,<br>Humalog Mix 50/50, Humulin R U-100,<br>Humulin N, Humulin 70/30   | Encourages the use of preferred insulin products unless not medically appropriate.<br>A quantity limit is applied to these agents.   |  |
| Narcolepsy                      | Nuvigil, Provigil<br>Xyrem is also included in this program.<br>See separate entry in Specialty Prior<br>Authorization section on next page.   | Encourages appropriate use when prescribed according to product labeling or for MS-related fatigue in patients age 17 and older. Upon meeting criteria, use of generic modafinil is typically required before the brands Nuvigil or Provigil. A quantity limit encourages FDA-approved dosing. Both brand and generic agents are targeted.   |  |
| Opioid Dependence               | Bunavail, Suboxone, Subutex, Zubsolv   | Helps ensure appropriate selection of patients for treatment according to product<br>labeling, clinical guidelines and/or clinical studies. A quantity limit encourages<br>FDA-approved dosing. Both brand and generic agents are targeted.  |  |

| Specialty Prior Authorization                   |  |  |
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| Drug Category                                   | Target Drugs   | Program Intent   |
| Cushing's Disease                               | Signifor   | Helps ensure appropriate use of Signifor in treatment of patients with Cushing's disease.  |
| Enzyme Deficiency                               | Kuvan  | Encourages use in patients with phenylketonuria (PKU) who are unable to maintain phenylalanine levels within the recommended range despite compliance with dietary restrictions. A quantity limit encourages FDA-approved dosing.  |
| Erythropoiesis<br>Stimulating Agents<br>(ESAs)  | Aranesp, Epogen, Procrit   | Encourages appropriate use of ESAs to ensure that hemoglobin levels are within an acceptable range.  |
| Familial<br>Hypercholesterolemia                | Juxtapid, Kynamro  | Helps ensure appropriate use of Juxtapid and Kynamro in treatment of patients with homozygous familial hypercholesterolemia (HoFH). A quantity limit encourages FDA-approved dosing.   |
| Growth Hormone/<br>Egrifta                      | Genotropin, Humatrope, Norditropin,<br>Nutropin, Nutropin AQ, Omnitrope, Saizen,<br>Serostim, Tev-tropin, Zorbtive | Encourages appropriate use for patients diagnosed with growth hormone<br>deficiencies. Upon meeting criteria, use of the formulary growth hormone<br>Omnitrope is typically required before non-formulary products. Also helps ensure<br>appropriate use of Egrifta in treatment of patients with HIV lipodystrophy. A quantity<br>limit for Egrifta encourages FDA-approved dosing.   |
| H.P. Acthar<br>(Pituitary Hormone)              | H.P. Acthar Gel  | Helps ensure that patients are appropriately selected for therapy according<br>to product labeling, clinical guidelines and/or clinical evidence. Verifies that<br>appropriate FDA-approved dosing is used for specified indications. FDA-approved<br>and/or clinically supported indications including, but not limited to, infantile<br>spasms.                                      |
| Hepatitis B & C                                 | Harvoni, Olysio, Pegasys, PegIntron,<br>Sovaldi  | Helps ensure that patients are appropriately selected and treated for an appropriate<br>duration of therapy according to parameters defined in product labeling, clinical<br>evidence and/or clinical guidelines. Upon meeting criteria, use of the formulary brand<br>pegylated interferon, Pegasys, is typically required before non-formulary products.                             |
|   | Infergen   | Helps ensure that patients are appropriately selected and treated for an appropriate duration of therapy according to parameters defined in product labeling, clinical evidence and/or clinical guidelines.  |
| Huntington's Chorea                             | Xenazine   | Encourages appropriate selection of patients for treatment of chorea associated with Huntington's disease. A quantity limit encourages FDA-approved dosing.  |
| ldiopathic<br>Thrombocytopenic<br>Purpura (ITP) | Nplate, Promacta   | Encourages appropriate, approved use for the treatment of chronic immune<br>(idiopathic) thrombocytopenic purpura in those who have had an insufficient<br>response to corticosteroids, immunoglobulins or splenectomy. A quantity limit<br>encourages FDA-approved dosing.  |
| Inherited<br>Autoinflammatory<br>Disorders      | Arcalyst, Ilaris   | Encourages use for FDA-approved indications and discourages use in place of anakinra for rheumatoid arthritis, and off-label uses. A quantity limit encourages FDA-approved dosing.  |
| Kalydeco (Cystic<br>Fibrosis)                   | Kalydeco   | Encourages appropriate selection of cystic fibrosis patients for treatment according to product labeling, clinical studies, and/or clinical guidelines while following dosing recommended in product labeling.   |
|   |  | For use in the treatment of cystic fibrosis (CF) in those 6 years of age and older with ONE of the CFTR gene mutations as indicated in the FDA label. If the patient's genotype is unknown, an FDA-cleared mutation test should be performed.  |
| Multiple Sclerosis                              | Ampyra   | Encourages appropriate use in ambulatory patients with multiple sclerosis.<br>A quantity limit encourages FDA-approved dosing.   |
| Osteoporosis                                    | Forteo   | Encourages use of first-line medications, bisphosphonates or selective estrogen receptor modulators (SERMs), prior to the use of Forteo in the treatment of patients with osteoporosis or very low bone mineral density (BMD) (T score $\leq$ -3.5) according to FDA-approved labeling, clinical studies and/or treatment guidelines. A quantity limit encourages FDA-approved dosing. |

## Specialty Prior Authorization (continued)

| Pulmonary Arterial<br>Hypertension (PAH) | Adcirca, Adempas, Letairis, Opsumit,<br>Orenitrum, Revatio, Tracleer  | Helps ensure appropriate selection of patients for treatment according to product<br>labeling, clinical studies and/or clinical guidelines. Upon meeting criteria, use of<br>generic sildenafil is typically required before the brands Adcirca or Revatio unless the<br>patient is already stabilized on the brand drug. A quantity limit encourages<br>FDA-approved dosing. Both brand and generic agents are targeted.  |
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| Self-administered<br>Oncology            | Afinitor, Afinitor Disperz, Bosulif, Caprelsa,<br>Cometriq, Erivedge, Gilotrif, Gleevec,<br>Hexalen, Hycamtin, Iclusig, Imbruvica,<br>Inlyta, Jakafi, Lysodren, Matulane, Mekinist,<br>Nexavar, Oforta, Pomalyst, Revlimid,<br>Sprycel, Stivarga, Sutent, Sylatron, Tafinlar,<br>Tarceva, Targretin, Tasigna, Temodar,<br>Thalomid, Tretinoin, Tykerb, Votrient, Xalkori,<br>Xeloda, Xtandi, Zelboraf, Zolinza, Zykadia,<br>Zydelig, Zytiga | Helps ensure appropriate selection of patients for treatment according to product<br>labeling, clinical studies and/or clinical guidelines. A quantity limit encourages<br>FDA-approved dosing.  |
| Short Bowel Syndrome                     | Gattex  | Helps ensure appropriate use of Gattex in the treatment of patients with short bowel syndrome (SBS).   |
| Urea Cycle Disorders                     | Buphenyl, Ravicti   | Helps ensure appropriate use of Buphenyl and Ravicti in patients with the following urea cycle disorders: carbamoylphosphate synthetase I deficiency (CPSID), ornithine transcarbamylase deficiency (OTCD), argininosuccinic acid synthetase deficiency (ASSD), argininosuccinic acid lyase deficiency (ASLD) or arginase deficiency (ARGD), who are not able to manage the disease by a protein restricted diet or with essential amino acid supplementation alone. |
| Xyrem                                    | Xyrem   | Encourages appropriate use in patients age 16 and older for the treatment<br>of cataplexy and as a second-line agent to a stimulant for patients with a<br>diagnosis of narcolepsy with excessive daytime sleepiness. A quantity limit<br>encourages FDA-approved dosing. <i>Part of the narcolepsy prior authorization program</i> .  |

| Step Therapy   |   |  |
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| Drug Category  | Target Drugs  | Program Intent   |
| Antidepressants  | Aplenzin, Brintellix, Celexa, Cymbalta,<br>desvenlafaxine ER tabs, Desvenlafaxine<br>fumarate, Effexor, Effexor XR, Fetzima,<br>fluoxetine 60 mg tabs, Forfivo XL,<br>Lexapro, Luvox CR, maprotiline, Oleptro,<br>Paxil, Paxil CR, Pexeva, Pristiq, Prozac,<br>Prozac Weekly, Remeron, Remeron<br>SolTab, venlafaxine ER tabs, Viibryd,<br>Viibryd Starter Kit, Wellbutrin, Wellbutrin<br>SR, Wellbutrin XL, Zoloft | Encourages use of cost-effective generic antidepressants for patients with<br>new prescriptions for brand agents. The criteria also encourages use of first-<br>line generic agents before Cymbalta when prescribed for neuropathic pain or<br>fibromyalgia.   |
| Cox-2/NSAID GI<br>Protectant (Pain<br>Management)                        | Celebrex, Duexis, Vimovo  | Encourages use of more cost-effective NSAID alternatives in patients who are not at high risk for an adverse gastrointestinal event. A quantity limit encourages FDA-approved dosing.  |
| Diabetes (GLP-1<br>Receptor Agonists)                                    | Bydureon, Byetta, Tanzeum, Trulicity,<br>Victoza  | Encourages appropriate use for patients with a diagnosis of type 2 diabetes<br>mellitus concomitantly treated with metformin; a sulfonylurea; a combination of<br>metformin and a sulfonylurea; a combination of metformin or sulfonylurea and<br>a thiazolidinedione or a basal insulin, such as Lantus or Levemir. A quantity limit<br>encourages FDA-approved dosing. |
| Glucose Test Strips  | All non-formulary brand test strips and disks   | Encourages use of cost-effective formulary glucose test strip products before non-formulary products. A quantity limit is applied to all glucose test strips.  |
| Lipid Management   | Advicor, Altoprev, Crestor, Lescol, Lescol<br>XL, Lipitor, Liptruzet, Livalo, Mevacor,<br>Pravachol, Simcor, Vytorin, Zocor   | Encourages use of cost-effective generic HMG CoA reductase inhibitor (HMG) agents prior to the use of non-formulary brand HMG or HMG combination agents for the management of high blood cholesterol.  |
| Proton Pump<br>Inhibitors – PPIs<br>(Gastroesophageal<br>Reflux Disease) | Aciphex, Dexilant, Esomeprazole<br>Strontium, First lansoprazole suspension<br>kit, First omeprazole suspension kit,<br>Nexium, omeprazole/sodium bicarbonate,<br>Prevacid, Prilosec, Protonix, Zegerid   | Encourages use of cost-effective generics prior to brand-name PPIs.<br>A quantity limit is applied to these agents.  |

| Specialty Step Therapy  |  |  |  |  |
|---|--|--|--|--|
| Drug Category   | Target Drugs   | Program Intent   |  |  |
| Biologic<br>Immunomodulators<br>(Rheumatoid<br>Arthritis/Psoriasis) | Actemra subcutaneous, Cimzia, Enbrel,<br>Entyvio, Humira, Humira starter kit,<br>Kineret, Orencia subcutaneous, Otezla,<br>Simponi, Stelara, Xeljanz | Upon meeting criteria, use of first-line medications is encouraged prior to the use of Humira and Enbrel. Also encourages use of one of the preferred biologic immunomodulators, Humira and Enbrel, before use of a non-preferred biologic immunomodulator. A quantity limit encourages FDA-approved dosing. |  |  |
| Iron Chelator   | Ferriprox  | Helps ensure appropriate use for transfusional iron overload due to thalassemia syndromes after the use of Exjade, based on FDA-approved labeling, clinical studies and/or treatment guidelines.   |  |  |
| Multiple Sclerosis  | Aubagio, Avonex, Extavia, Gilenya  | Encourages use of formulary agents prior to use of non-formulary agents.<br>Coverage is allowed for only one disease-modifying agent at a time. A quantity<br>limit encourages FDA-approved dosing.  |  |  |

These programs are included in the standard utilization management package and apply for most standard pharmacy benefit plans. Not all drug categories are included in all plans. Refer to the member's benefit materials or call the number on the back of the member's Blue Cross and Blue Shield of Montana ID card to determine whether a particular category is part of the member's benefit.

This list is subject to change without notice. Call 888-723-7443 to confirm the status of a particular drug.

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