**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 January 15, 2015 Pharmacy and Therapeutics (P&T) Advisory Committee Meeting.

| Description of Recommendation | Final Decision (s) |
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| **New Products to Market: Jardiance®**<br>Empagliflozin (Jardiance®) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Invokamet™**<br>Invokamet™ (canagliflozin/metformin) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Xigduo XR™**<br>Xigduo XR™ (dapagliflozin/metformin ER) should only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Trulicity™**<br>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: Auryxia™**<br>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: Aptiom®**<br>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: Striverdi® Respimat®**<br>Place this product non preferred with similar quantity limits in the PDL class titled Long-Acting Beta Agonists. | 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: Rasuvo™**<br>Rasuvo™ (methotrexate) will only be approved for the following diagnoses:<br>• Rheumatoid arthritis (RA) after trial and failure of:<br>o NSAID; and<br>o Corticosteroid; and<br>o Oral methotrexate; OR<br>• Polyarticular juvenile idiopathic arthritis (pJIA) after trial and failure of:<br>o NSAID; and<br>o Corticosteroid; and<br>o Oral methotrexate; OR<br>• Psoriasis after trial and failure of:<br>o Topical agents for the treatment of psoriasis (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, and/or topical tacrolimus, pimecrolimus); AND<br>o Oral methotrexate. | The final prior approval criteria will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Zykadia™**<br>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. |
| **New Products to Market: Zydelig®**<br>Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology Agents; however, only approve idelalisib (Zydelig®) for one of the following diagnoses:<br>• Chronic lymphocytic leukemia (CLL), in combination with rituximab; OR<br>• Follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies; OR<br>• Small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Akynzeo®**<br>Place this product non preferred with appropriate quantity limits in the PDL class titled Oral Anti-Emetics: NK-1 Antagonists. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **New Products to Market: Kerydin™**<br>Place this product non preferred in the PDL class titled Topical Antifungal Agents; however, only approve Tavaborole (Kerydin™) 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. |

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| **New Products to Market: Harvoni®**<br>Place this product preferred with appropriate quantity and duration limits in the PDL class titled Hepatitis C: NS5B Polymerase Inhibitors; however, only approve ledipasvir/sofosbuvir (Harvoni®) if ALL of the following are true:<br>• Age ≥18 years old; AND<br>• Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND<br>• Patient is treatment-naïve to ledipasvir and/or sofosbuvir. Limited to one course of therapy per lifetime.; AND<br>• Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND<br>• Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND<br>• Patient has been evaluated for and *does not* have clinically significant drug interactions (i.e., certain acid reducing agents, antiarrhythmics, HIV Antiretroviral medications, anticonvulsants, antimycobacterials, herbal supplements, HMG-CoA Reductase Inhibitors); AND<br>• Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m$^2$) or end stage renal disease (ESRD) requiring hemodialysis; AND<br>• Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND<br>• Patient has not actively participated in illicit substance abuse or alcohol abuse for 6 months prior to or during therapy attested by the prescribing physician(s) AND using one of the following confirmation tests administered both randomly and periodically throughout treatment:<br>o Patient has been evaluated for current substance abuse and alcohol with validated screening instruments such as Alcohol Use Disorders Identification Test (AUDIT C) or CAGE alcohol screen, or National Institute on Drug Abuse's (NIDA's) drug screening tool; OR<br>▪ Acceptable alcohol consumption tests include: Serum gamma-glutamyl | The final PDL placement will be determined after a review of this product at the next P&T meeting. |

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| transpeptidase (GGT), mean corpuscular volume (MCV), carbohydrate-deficient transferrin (CDT), and urine ethylglucuronide (EtG) tests. Results must be documented in the patient's medical record to include, results of testing, and date tested; AND<br>▪ Urine toxicology screen results for substance abuse are acceptable in lieu of the actual laboratory drug screen report. Results must be documented in the patient's medical record to include substances tested, results of testing, and date tested; AND<br>• If patient has a prior history of substance or alcohol abuse, the patient has completed or is participating in a recovery program, or receiving substance or alcohol abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND<br>• Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND<br>• Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as:<br>o Disease Severity (patient **MUST** have one of the following):<br>▪ Liver biopsy showing Metavir score of F3/F4; **OR**<br>▪ Ultrasound based transient elastography (Fibroscan) score ≥ 9.5 kPa; **OR**<br>▪ Evidence of any **TWO** of the following:<br>➢ Fibrotest (FibroSure) score of ≥ 0.59<br>➢ Fibrosis-4 index (FIB-4) > 3.25<br>➢ Aspartate aminotransferase/platelet ratio index (APRI) score of > 1.5<br>➢ Cirrhotic features on imaging<br>➢ Physical exam consistent with cirrhosis; AND/OR<br>o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following):<br>Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR**<br>▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** | |

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| ▪ Proteinuria; **OR**<br>▪ Nephrotic Syndrome; **OR**<br>▪ Membranoproliferative glomerulonephritis; AND<br>• One of the following diagnoses:<br>o For diagnosis of chronic HCV with genotype 1, approve for 8 weeks of therapy IF patient meets ALL of the following criteria:<br>▪ Treatment-naïve; AND<br>▪ Have documented baseline HCV RNA of less than 6 million IU/mL; AND<br>▪ Without cirrhosis (Metavir F4).<br>o For diagnosis of chronic HCV with genotype 1:<br>▪ Approve for an initial 8 weeks of therapy IF patient meets ONE of the following criteria:<br>➢ Treatment-naïve with cirrhosis (Metavir F4) or without cirrhosis and baseline HCV RNA greater than 6 million IU/mL; OR<br>➢ Treatment experienced without cirrhosis (Metavir F4).<br>▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria:<br>➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND<br>➢ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND<br>➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).<br>o For diagnosis of chronic HCV with genotype 1:<br>▪ Approve for and initial 8 weeks of therapy for treatment experienced patients with cirrhosis (Metavir F4).<br>▪ Approve for an additional 8 weeks (16 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria:<br>➢ The patient has been compliant with drug therapy regimen (per pharmacy | |

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| paid claims history); AND<br>➢ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND<br>➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4)<br>▪ Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria:<br>➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND<br>➢ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing physician(s) AND using the same verification documentation listed for original authorization; AND<br>➢ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12) | |
| **<u>Omalizumab (Xolair®) Clinical Criteria</u>**<br>Initial Therapy (6 months):<br>Xolair® (omalizumab) will be approved initially for the following diagnoses:<br>• Moderate to severe asthma (step 5 or higher) if ALL of the following are true:<br>o 12 years of age or older; AND<br>o Positive skin test or in vitro reactivity to a perennial aeroallergen; AND<br>o FEV1 of <80% while on asthma controller medication; AND<br>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.<br>• Chronic idiopathic urticaria if ALL of the following are true:<br>o 12 years of age or older; AND<br>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) | The final prior approval criteria will be determined after a review of this product at the next P&T meeting. |

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| of urticaria; AND<br>o One of the following:<br>▪ 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<br>▪ 3-month trial and failure of one antihistamine products and one (1) of the following leukotriene antagonists: montelukast OR zafirlukast and patient has documented ongoing symptoms of chronic idiopathic urticaria; AND<br>o A baseline urticaria activity score (UAS7) is required before approval. Renewals will require submission of a new UAS7 (within previous 30 days of renewal).<br><br>Continuation of Therapy:<br>Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses:<br>• Moderate to severe asthma (step 5 or higher) if one of the following is true:<br>o During previous treatment with omalizumab, the patient experienced a reduction in asthma exacerbations (e.g., hospitalizations, urgent or emergent care visits, use of rescue medications, etc.) from their pre- omalizumab baseline, OR<br>o The patient was receiving maintenance therapy with an oral corticosteroid prior to initiation of omalizumab and the patient has been able to reduce their oral corticosteroid dose to less than their pre-omalizumab baseline or to ≤ 5 mg daily, OR<br>o The patient was receiving maintenance therapy with an inhaled corticosteroid prior to initiation of omalizumab and the patient has been able to reduce their inhaled corticosteroid dose to less than their pre-omalizumab baseline.<br>• Chronic idiopathic urticaria if ALL of the following are true:<br>o Treatment with omalizumab has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; AND<br>o Submitted current UAS7 was recorded within the past 30 days. | |

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| **Apolipoprotein B Synthesis Inhibitors**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require PA.<br>3. For any new chemical entity in the Apolipoprotein B Synthesis Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. | The final PDL placement will be determined after a review of this product at the next P&T meeting. |
| **Apolipoprotein B Synthesis Inhibitors Clinical Criteria**<br>Approval of Apolipoprotein B Synthesis Inhibitors will be granted as described below.<br>• For initial treatment, approve for 6 months if ALL of the following are true:<br>o Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND<br>o Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND<br>o Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND<br>o Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment and required for renewal; AND<br>o Patient tried and failed at least a 3 month trial of the maximally tolerated dose with two (2) of the following statins: simvastatin 40mg (Zocor®), atorvastatin 80mg (Lipitor®) OR rosuvastatin 40mg (Crestor®), unless contraindicated; AND<br>o Patient tried and failed at least a 3 month trial combination with both ezetimibe 10mg (Zetia®) AND atorvastatin 80mg (Lipitor®) OR simvastatin 40mg (Zocor®), unless contraindicated; AND<br>o Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL cholesterol ≥ 330 mg/dL).<br>• For continuation of treatment, approve for one year | The final criteria will be determined after a review of this product at the next P&T meeting. |

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| if ALL of the following are true:<br>o Documented reduction of low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) from baseline; AND<br>o Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND<br>o Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: elevations in transaminases (ALT, AST), hepatic steatosis, serious injection site reactions, and flu-like symptoms. | |
| **Platelet Aggregation Inhibitors**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least four unique chemical entities should be preferred. Based on the clinical merits, place in therapy and utilization of clopidogrel, it must be a preferred agent.<br>2. Continue to allow ticagrelor products for use in patients with Acute Coronary Syndrome (ACS).<br>3. Agents not selected as preferred will be considered non preferred and require PA.<br>4. For any new chemical entity in the Platelet Aggregation Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Aggrenox®<br>Brilinta™<br>cilostazol<br>clopidogrel<br>dipyridamole<br><br>Non Preferred Agent (s)<br>Effient™<br>Persantine®<br>Plavix®<br>Pletal®<br>ticlopidine<br>Zontivity™ |
| **Anticoagulants**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one low molecular weight heparin, one factor Xa inhibitor, and two oral anticoagulants should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require PA.<br>3. For any new chemical entity in the Anticoagulants class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Eliquis®<br>enoxaparin<br>fondaparinux<br>Fragmin®<br>Pradaxa®<br>warfarin<br>Xarelto®<br><br>Non Preferred Agent (s)<br>Arixtra™<br>Coumadin®<br>Lovenox® |

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| **Vasodilator and Nitrate Combination**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one unique chemical entity should be preferred.<br>2. Agents not selected as preferred will be considered non preferred and require PA.<br>3. For any new chemical entity in the Vasodilator and Nitrate Combination class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>BiDil®<br><br>Non Preferred Agent (s)<br>N/A |
| **Anti-Anginal & Anti-Ischemic Agent**<br>1. DMS to select preferred agent (s) based on economic evaluation.<br>2. Agents not selected as preferred will be considered non preferred and require PA.<br>3. For any new chemical entity in the Anti-Anginal & Anti-Ischemic Agent class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Ranexa®<br><br>Non Preferred Agent (s)<br>N/A |
| **Anti-Anginal & Anti-Ischemic Agent Clinical Criteria**<br>Anti-Anginal & Anti-Ischemic Agents will be approved if the patient has tried and failed therapy with any one of the following drug classes within the past 90 days (unless ALL are contraindicated):<br>• Beta Blocker, OR<br>• Nitrate, OR<br>• Calcium Channel Blocker. | Anti-Anginal & Anti-Ischemic Agents will be approved if the patient has tried and failed therapy with any one of the following drug classes within the past 90 days (unless ALL are contraindicated):<br>• Beta Blocker, OR<br>• Nitrate, OR<br>• Calcium Channel Blocker. |

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| **Oral Anti-Arrhythmics**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least six unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Oral Antiarrhythmics class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>amiodarone 100, 200 mg<br>disopyramide<br>flecainide<br>mexiletine<br>procainamide<br>propafenone<br>quinidine gluconate ER<br>quinidine sulfate<br>quinidine sulfate ER<br>sotalol<br>Tikosyn®<br><br>Non Preferred Agent (s)<br>amiodarone 400 mg<br>Betapace®<br>Cordarone®<br>Multaq®<br>Norpace®<br>Norpace® CR<br>Pacerone®<br>Pronestyl®<br>propafenone sustained-release<br>Rythmol®<br>Rythmol® SR<br>Tambocor® |

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| **Pulmonary Arterial Hypertension (PAH) Agents**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent representing three of the unique mechanisms of should be preferred.<br>2. Sildenafil and tadalafil should be subject to prior authorization criteria to ensure they are being used for PAH.<br>3. If riociguat is not selected as a preferred agent, it will be available for a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH).<br>4. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>5. Allow continuation of therapy for non preferred single source branded products via a 90 day look back.<br>6. For any new chemical entity in the Pulmonary Arterial Hypertension Agents class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Letairis™<br>sildenafil<br>Tracleer®<br>Ventavis®<br><br>Non Preferred Agent (s)<br>Adcirca™<br>Adempas®<br>Opsumit®<br>Orenitram™<br>Revatio™<br>Tyvaso™ |
| **Proton Pump Inhibitors**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. Additionally, at least one dosage form suitable for pediatric use should be preferred.<br>2. Continue current quantity limits on all agents in this class.<br>3. Agents not selected as preferred will be considered non preferred and require PA.<br>4. For any new chemical entity in the Proton Pump Inhibitors class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Nexium®<br>omeprazole capsules<br>pantoprazole<br><br>Non Preferred Agent (s)<br>Aciphex®<br>Dexilant™<br>esomeprazole strontium<br>lansoprazole<br>omeprazole suspension<br>omeprazole/sodium bicarbonate<br>Prevacid®<br>Prilosec®<br>Protonix®<br>rabeprazole<br>Zegerid® |

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| **Histamine$_2$-Receptor Antagonists**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Histamine$_2$-Receptor Antagonists class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>cimetidine<br>famotidine tablets<br>ranitidine tablets<br><br>Non Preferred Agent (s)<br>Axid®<br>famotidine suspension<br>nizatidine<br>Pepcid®<br>ranitidine capsules<br>Zantac® |
| **Anti-Ulcer Protectants**<br>1. DMS to select preferred agent (s) based upon economic evaluation; however, at least two unique chemical entities should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. For any new chemical entity in the Anti-Ulcer Protectants class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Carafate® suspension<br>misoprostol<br>sucralfate<br><br>Non Preferred Agent (s)<br>Carafate® tablets<br>Cytotec® |
| ***H. pylori* Treatment**<br>1. DMS to select preferred agent (s) based on economic evaluation; however, at least one agent containing a Proton Pump Inhibitor (PPI), clarithromycin and either amoxicillin or metronidazole should be preferred.<br>2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization.<br>3. Agents in this class should have quantity limits based on the FDA-approved maximum dose.<br>4. For any new chemical entity in the *H. pylori* Treatment class, require a PA until reviewed by the P&T Advisory Committee. | Selected Preferred Agent (s)<br>Helidac®<br>Prevpac®<br>Pylera®<br><br>Non Preferred Agent (s)<br>lansoprazole, amoxicillin, clarithromycin<br>Omeclamox-Pak™ |