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 March 19, 2015 Pharmacy and Therapeutics (P&T) Advisory Committee Meeting.

Description of Recommendation	Final Decision (s)
New Products to Market: Jardiance® 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.	Empagliflozin (Jardiance®) will only be approved for patients with a diagnosis of type 2 diabetes who have tried and failed maximum tolerated doses of metformin.
New Products to Market: Invokamet™ 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.	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.
New Products to Market: Xigduo XR™ 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.	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.
New Products to Market: Trulicity™ 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: Afrezza® Place this product non preferred in the PDL class titled Insulins.	The final PDL placement will be determined after a review of this product at the next P&T meeting.
New Products to Market: Auryxia™ Place this product non preferred in the PDL class titled Phosphate Binders.	Auryxia™ will be placed non preferred in the PDL class titled Phosphate Binders.
New Products to Market: Aptiom® Place this product non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.	Aptiom® will be placed non preferred in the PDL class titled Anticonvulsants: Carbamazepine Derivatives.
New Products to Market: Belsomra® Place this product non preferred with appropriate quantity limits in the PDL class titled Sedative Hypnotics.	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® Place this product non preferred with similar quantity limits in the PDL class titled Long-Acting Beta Agonists.	Striverdi® Respimat® will be placed non preferred with similar quantity limits in the PDL class titled Long-Acting Beta Agonists.
New Products to Market: Incruse™ Ellipta® Place this product non preferred with similar quantity limits in the PDL class titled COPD Agents.	Incruse™ Ellipta® will be placed non preferred with similar quantity limits in the PDL class titled COPD Agents.

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New Products to Market: Arnuity™ Ellipta® Place this product non preferred with similar quantity limits in the PDL class titled Inhaled Corticosteroids.	Arnuity™ Ellipta® will be placed non preferred with similar quantity limits in the PDL class titled Inhaled Corticosteroids.
New Products to Market: Rasuvo™ Rasuvo™ (methotrexate) will only be approved for the following diagnoses: • Rheumatoid arthritis (RA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR • Polyarticular juvenile idiopathic arthritis (pJIA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR • Psoriasis after trial and failure of: o Topical agent for the treatment of psoriasis (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, and/or topical tacrolimus, pimecrolimus); AND o Oral methotrexate.	Rasuvo™ (methotrexate) will only be approved for the following diagnoses: • Rheumatoid arthritis (RA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR • Polyarticular juvenile idiopathic arthritis (pJIA) after trial and failure of: o NSAID; and o Corticosteroid; and o Oral methotrexate; OR • Psoriasis after trial and failure of: o Topical agent for the treatment of psoriasis (e.g., emollients, corticosteroids, retinoids, vitamin D analogs, and/or topical tacrolimus, pimecrolimus); AND o Oral methotrexate.
New Products to Market: Zykadia™ Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology, Lung Cancer.	Zykadia™ will be placed non preferred with similar quantity limits in the PDL class titled Oral Oncology, Lung Cancer.
New Products to Market: Zydelig® Place this product preferred with similar quantity limits in the PDL class titled Oral Oncology, Hematologic Cancer; however, only approve idelalisib (Zydelig®) for one of the following diagnoses: • Chronic lymphocytic leukemia (CLL), in combination with rituximab; OR • Follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies; OR • Small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.	Zydelig® will be placed preferred with similar quantity limits in the PDL class titled Oral Oncology, Hematologic Cancer; however, it will only be approved for one of the following diagnoses: • Chronic lymphocytic leukemia (CLL), in combination with rituximab; OR • Follicular B-cell non-Hodgkin lymphoma (FL) in patients who have received at least two prior systemic therapies; OR • Small lymphocytic lymphoma (SLL) in patients who have received at least two prior systemic therapies.

Description of Recommendation	Final Decision (s)
New Products to Market: Lynparza™ Place this product non preferred with similar quantity limits in the PDL class titled Oral Oncology, Other; however, approve olaparib (Lynparza™) once the following criteria are met. • Initial approval criteria include: o Patient must be at least 18 years of age; **AND** o Patient's disease must be advanced (i.e. Stage II or greater disease in which the cancer has spread to other areas of the pelvis or beyond); **AND** o Patient must have germline BRCA (gBRCA) mutated disease (as detected by an FDA-approved test i.e. BRACAnalysis CDx™); **AND** o Must be used as a single agent; **AND** o Patient must have received treatment with three or more prior lines of chemotherapy; **AND** o Patient has an ECOG performance status of 0-1. • Renewal criteria include: o Patient continues to meet initial review criteria; **AND** o Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND** o Absence of unacceptable toxicity from the drug (e.g. anemia, nausea, fatigue, vomiting, diarrhea, dysgeusia, dyspepsia, headache, decreased appetite, upper respiratory tract infection, cough, arthralgia, myalgia, back pain, dermatitis, rash, abdominal discomfort); **AND** o Patient has not developed myelodysplastic syndrome/acute myeloid leukemia (MDS/AML); **AND** o Patient has not developed pneumonitis.	Lynparza™ will be placed non preferred with similar quantity limits in the PDL class titled Oral Oncology, Other; however, approve olaparib (Lynparza™) once the following criteria are met. • Initial approval criteria include: o Patient must be at least 18 years of age; **AND** o Patient's disease must be advanced (i.e. Stage II or greater disease in which the cancer has spread to other areas of the pelvis or beyond); **AND** o Patient must have germline BRCA (gBRCA) mutated disease (as detected by an FDA-approved test i.e. BRACAnalysis CDx™); **AND** o Must be used as a single agent; **AND** o Patient must have received treatment with three or more prior lines of chemotherapy; **AND** o Patient has an ECOG performance status of 0-1. • Renewal criteria include: o Patient continues to meet initial review criteria; **AND** o Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND** o Absence of unacceptable toxicity from the drug (e.g. anemia, nausea, fatigue, vomiting, diarrhea, dysgeusia, dyspepsia, headache, decreased appetite, upper respiratory tract infection, cough, arthralgia, myalgia, back pain, dermatitis, rash, abdominal discomfort); **AND** o Patient has not developed myelodysplastic syndrome/acute myeloid leukemia (MDS/AML); **AND** o Patient has not developed pneumonitis.
New Products to Market: Akynzeo® Place this product non preferred with appropriate quantity limits in the PDL class titled Oral Anti-Emetics: NK-1 Antagonists.	Akynzeo® will be placed non preferred with appropriate quantity limits in the PDL class titled Oral Anti-Emetics: NK-1 Antagonists.

Description of Recommendation	Final Decision (s)
New Products to Market: Kerydin™ 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.	Kerydin™ will be placed non preferred in the PDL class titled Topical Antifungal Agents; however, it will only be approved for a diagnosis of toenail onychomycosis after trial and failure of one other agent indicated for the treatment of onychomycosis.
New Products to Market: Soolantra® Place this product non preferred in the PDL class titled Topical Rosacea Agents.	Soolantra® will be placed non preferred in the PDL class titled Topical Rosacea Agents.
New Products to Market: Viekira Pak™ Place this product preferred with appropriate quantity and duration limits in the PDL class titled Direct-Acting Antiviral Agents; however, only approve ombitasvir/paritaprevir/ritonavir/dasabuvir (Viekira Pak™) if ALL of the following are true: • Age ≥18 years old; AND • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to all parts of the dasabuvir/ombitasvir/paritaprevir therapy. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND • Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • Patient has been evaluated for and *does not* have clinically significant drug interactions (i.e., antiarrhythmics, antifungals, calcium channel blockers, corticosteroids, diuretics, immunosuppressants, narcotic analgesics, sedative/hypnotics, HMG-CoA Reductase Inhibitors, proton pump inhibitors, HIV Antivirals, long acting beta-agonists); AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • 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	Viekira Pak™ will be placed preferred with appropriate quantity and duration limits in the PDL class titled Direct-Acting Antiviral Agents; however, it will only be approved if ALL of the following are true: • Age ≥18 years old; AND • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to all parts of the dasabuvir/ombitasvir/paritaprevir therapy. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND • Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • Patient has been evaluated for and *does not* have clinically significant drug interactions (i.e., antiarrhythmics, antifungals, calcium channel blockers, corticosteroids, diuretics, immunosuppressants, narcotic analgesics, sedative/hypnotics, HMG-CoA Reductase Inhibitors, proton pump inhibitors, HIV Antivirals, long acting beta-agonists); AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • 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

periodically throughout treatment: 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 ▪ Acceptable alcohol consumption tests include: Serum gamma-glutamyl 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 ▪ 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 • 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 • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: o Disease Severity (patient **MUST** have one of the following): ▪ Liver biopsy showing Metavir score of F2-F4; **OR** ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR** ▪ Evidence of any **TWO** of the following: ➢ Fibrotest (FibroSure) score of ≥ 0.49 ➢ Fibrosis-4 index (FIB-4) > 3.25 ➢ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ➢ Cirrhotic features on imaging ➢ Physical exam consistent with cirrhosis; **AND/OR**	randomly and periodically throughout treatment: 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 ▪ Acceptable alcohol consumption tests include: Serum gamma-glutamyl 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 ▪ 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 • 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 • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: o Disease Severity (patient **MUST** have one of the following): ▪ Liver biopsy showing Metavir score of F2-F4; **OR** ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR** ▪ Evidence of any **TWO** of the following: ➢ Fibrotest (FibroSure) score of ≥ 0.49 ➢ Fibrosis-4 index (FIB-4) > 3.25

o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): ▪ Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** ▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** ▪ Proteinuria; **OR** ▪ Nephrotic Syndrome; **OR** ▪ Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: o For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **does not** have cirrhosis; AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Patient is treatment naïve or treatment experienced with prior relapse or partial response; AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting	➢ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ➢ Cirrhotic features on imaging ➢ Physical exam consistent with cirrhosis; **AND/OR** o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): ▪ Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** ▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** ▪ Proteinuria; **OR** ▪ Nephrotic Syndrome; **OR** ▪ Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: o For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **does not** have cirrhosis; AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).

dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1a approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Treatment experienced with prior null response ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ▪ Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria:	o For diagnosis of chronic HCV with genotype 1a, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Patient is treatment naïve or treatment experienced with prior relapse or partial response; AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1a approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Treatment experienced with prior null response ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with

➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12) o For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **does not** have cirrhosis; AND ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ The patient is not actively participating	drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). ▪ Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12) o For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **does not** have cirrhosis; AND ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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

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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).	➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1b, approve for an initial 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Patient **has** cirrhosis (Metavir F4); AND ▪ Patient has concurrent (or planning to start) therapy with ribavirin when starting dasbuvir + ombitasvir/paritaprevir/ritonavir for a 12 week duration ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4).
<u>New Products to Market: Harvoni®</u> Place this product non preferred with appropriate quantity and duration limits in the PDL class titled Direct-Acting Antiviral Agents; however, only approve ledipasvir/sofosbuvir (Harvoni®) if ALL of the following are true: • Patient has tried and failed, unless contraindicated, one preferred product. • Age ≥18 years old; AND • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to ledipasvir and/or sofosbuvir. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir	Harvoni® will be placed non preferred with appropriate quantity and duration limits in the PDL class titled Direct-Acting Antiviral Agents; however, it will only be approved if ALL of the following are true: • Patient has tried and failed, unless contraindicated, one preferred product. • Age ≥18 years old; AND • Must be prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease physician; AND • Patient is treatment-naïve to ledipasvir and/or sofosbuvir. Limited to one course of therapy per lifetime.; AND • Patient is *not* receiving concomitant therapy with a hepatitis C protease inhibitor (e.g., telaprevir [Incivek®], boceprevir [Victrelis®], simeprevir [Olysio®]); AND

[Olysio®]); AND • Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • 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 • Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • 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: 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 ▪ Acceptable alcohol consumption tests include: Serum gamma-glutamyl 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 ▪ 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 • 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	• Patient does *not* have decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND • 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 • Patient does *not* have severe renal impairment (eGFR <30 mL/min/1.73m^2) or end stage renal disease (ESRD) requiring hemodialysis; AND • Patient does *not* have a diagnosis of HCV genotypes 2, 3, 4, 5, or 6; AND • 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: 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 ▪ Acceptable alcohol consumption tests include: Serum gamma-glutamyl 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 ▪ 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 • If patient has a prior history of substance or

addiction specialist as part of HCV treatment; AND • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: o Disease Severity (patient **MUST** have one of the following): ▪ Liver biopsy showing Metavir score of F2-F4; **OR** ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR** ▪ Evidence of any **TWO** of the following: ➢ Fibrotest (FibroSure) score of ≥ 0.49 ➢ Fibrosis-4 index (FIB-4) > 3.25 ➢ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ➢ Cirrhotic features on imaging ➢ Physical exam consistent with cirrhosis; **AND/OR** o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): ▪ Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** ▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** ▪ Proteinuria; **OR** ▪ Nephrotic Syndrome; **OR** ▪ Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: o For diagnosis of chronic HCV with genotype 1, approve for 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Treatment-naïve; AND ▪ Have documented baseline HCV RNA of less than 6 million IU/mL; AND ▪ Without cirrhosis (Metavir F4). o For diagnosis of chronic HCV with genotype 1: ▪ Approve for an initial 8 weeks of therapy IF patient meets ONE of the following criteria: ➢ Treatment-naïve with cirrhosis (Metavir F4); 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 • Baseline HCV-RNA is submitted. HCV RNA levels will be required at treatment weeks 4, and 12 for renewals; AND • Have documentation of Disease Severity **AND/OR** Highest Risk for Disease Progression, defined as: o Disease Severity (patient **MUST** have one of the following): ▪ Liver biopsy showing Metavir score of F2-F4; **OR** ▪ Ultrasound based transient elastography (Fibroscan) score ≥ 7.1 kPa; **OR** ▪ Evidence of any **TWO** of the following: ➢ Fibrotest (FibroSure) score of ≥ 0.49 ➢ Fibrosis-4 index (FIB-4) > 3.25 ➢ Aspartate aminotransferase/platelet ratio index (APRI) score of > 0.5 ➢ Cirrhotic features on imaging ➢ Physical exam consistent with cirrhosis; **AND/OR** o Documentation showing patient at the highest risk for severe complications (patient **MUST** have one of the following): ▪ Advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4); **OR** ▪ Essential mixed cryoglobulinemia with end organ manifestations (including arthralgias, palpable purpura, peripheral neuropathy, central nervous system vasculitis); **OR** ▪ Proteinuria; **OR** ▪ Nephrotic Syndrome; **OR** ▪ Membranoproliferative glomerulonephritis; AND • One of the following diagnoses: o For diagnosis of chronic HCV with genotype 1, approve for 8 weeks of therapy IF patient meets ALL of the following criteria: ▪ Treatment-naïve; AND ▪ Have documented baseline HCV RNA

➢ Treatment-naïve without cirrhosis and baseline HCV RNA greater than 6 million IU/mL; OR ➢ Treatment experienced without cirrhosis (Metavir F4). ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1: ▪ Approve for and initial 8 weeks of therapy for treatment experienced patients with cirrhosis (Metavir F4). ▪ Approve for an additional 8 weeks (16 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4) ▪ Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND	of less than 6 million IU/mL; AND ▪ Without cirrhosis (Metavir F4). o For diagnosis of chronic HCV with genotype 1: ▪ Approve for an initial 8 weeks of therapy IF patient meets ONE of the following criteria: ➢ Treatment-naïve with cirrhosis (Metavir F4); OR ➢ Treatment-naïve without cirrhosis and baseline HCV RNA greater than 6 million IU/mL; OR ➢ Treatment experienced without cirrhosis (Metavir F4). ▪ Approve for an additional 4 weeks (12 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4). o For diagnosis of chronic HCV with genotype 1: ▪ Approve for and initial 8 weeks of therapy for treatment experienced patients with cirrhosis (Metavir F4). ▪ Approve for an additional 8 weeks (16 weeks total) of therapy (Authorization #2) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ The patient is not actively participating in illicit substance abuse or alcohol abuse during therapy attested by the prescribing

➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12)	physician(s) AND using the same verification documentation listed for original authorization; AND ➢ HCV RNA levels are < 25 IU/mL at treatment week 4 (TW4) ▪ Approve for an additional 8 weeks (24 weeks total) of therapy (Authorization #3) IF patient meets ALL of the following criteria: ➢ The patient has been compliant with drug therapy regimen (per pharmacy paid claims history); AND ➢ 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 ➢ HCV RNA levels are < 25 IU/mL at treatment week 12 (TW12)
Omalizumab (Xolair®) Clinical Criteria Initial Therapy (6 months): Xolair® (omalizumab) will be approved initially 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 One of the following: ▪ 3-month trial and failure of two (2) H1	Initial Therapy (6 months): Xolair® (omalizumab) will be approved initially 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 One of the following:

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: montelukast OR zafirlukast and patient has documented ongoing symptoms of chronic idiopathic urticaria; AND 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). <u>Continuation of Therapy:</u> Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses: • Moderate to severe asthma (step 5 or higher) if one of the following is true: 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 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 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. • Chronic idiopathic urticaria if ALL of the following are true: o Treatment with omalizumab has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; **AND** o Submitted current UAS7 was recorded within the past 30 days.	▪ 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: montelukast OR zafirlukast and patient has documented ongoing symptoms of chronic idiopathic urticaria; AND 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). <u>Continuation of Therapy:</u> Xolair® (omalizumab) will be approved for continuation of therapy for the following diagnoses: • Moderate to severe asthma (step 5 or higher) if one of the following is true: 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 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 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. • Chronic idiopathic urticaria if ALL of the following are true: o Treatment with omalizumab has resulted in clinical improvement as documented by improvement (decrease) in urticaria activity score (UAS7) from baseline; **AND** o Submitted current UAS7 was recorded within the past 30 days.

Description of Recommendation	Final Decision (s)
Apolipoprotein B Synthesis Inhibitors 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 Apolipoprotein B Synthesis Inhibitors class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) Kynamro™ Non Preferred Agent (s) Juxtapid™
Apolipoprotein B Synthesis Inhibitors Clinical Criteria Approval of Apolipoprotein B Synthesis Inhibitors will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND o Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND o Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND 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 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 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 o Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL cholesterol ≥ 330 mg/dL).	Approval of Apolipoprotein B Synthesis Inhibitors will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Diagnosis of homozygous familial hypercholesterolemia (HoFH) with untreated total cholesterol (TC) >500 mg/dL; AND o Must be used as an adjunct to a low-fat diet supplying < 20% of energy from fat; AND o Baseline alanine and aspartate aminotransferases (ALT, AST), alkaline phosphatase, and total bilirubin lab values must be obtained prior to initiating treatment; AND 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 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 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 o Despite the pharmacological treatment with statins and ezetimibe, patient's LDL cholesterol ≥ 300 mg/dL (or non-HDL

• For continuation of treatment, approve for one year if ALL of the following are true: 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 o Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND 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.	cholesterol ≥ 330 mg/dL). • For continuation of treatment, approve for one year if ALL of the following are true: 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 o Documentation of dosage adjustment if ALT or AST is ≥ 3 times the upper limit of normal (ULN); AND 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.
Hepatitis C: Direct-Acting Antiviral Agents 1. DMS to select preferred agent (s) based on economic evaluation; however at least one unique chemical entity should be preferred. 2. Continue quantity limits based on FDA-approved maximum dose and duration. 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 Hepatitis C: Direct-Acting Antiviral 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 product at the next P&T meeting.

Description of Recommendation	Final Decision (s)
Oral Oncology, Lung Cancer 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type 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, Lung Cancer 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.
Oral Oncology, Renal Cell Carcinoma 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type 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, Renal Cell Carcinoma 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.

Description of Recommendation	Final Decision (s)
Oral Oncology, Breast Cancer 1. DMS to select preferred agent(s) based on economic evaluation; however, at least tamoxifen and one Aromatase Inhibitor 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, Breast Cancer 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.
Oral Oncology, Prostate Cancer 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type 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, Prostate Cancer 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.

Description of Recommendation	Final Decision (s)
Oral Oncology, Hematologic Cancer 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type should be preferred. Due to 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, Hematologic Cancer 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.
Oral Oncology, Other 1. DMS to select preferred agent(s) based on economic evaluation; however, at least one oral agent representing a Category 1 recommendation by the NCCN for each cancer type 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, Other 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.

Description of Recommendation	Final Decision (s)
Oral Anti-Emetics: 5-HT3 Antagonists 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 will require Prior Authorization. 3. For any new chemical entity in the Oral Anti-Emetics: 5-HT3 Antagonists, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) ondansetron Non Preferred Agent (s) Aloxi® Anzemet® granisetron Granisol™ Sancuso® Zofran® Zuplenz®
Oral Anti-Emetics: NK_1 Antagonist 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 will require Prior Authorization. 3. For any new chemical entity in the Oral Anti-Emetics: NK1 antagonist, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) Emend® Non Preferred Agent (s) Akynzeo®
Oral Anti-Emetics: Δ-9-THC Derivatives 1. DMS to select preferred agent (s) based on economic evaluation; however at least one unique chemical entity should be preferred. 2. All agents in this category should require Prior Authorization to prevent miss-use. 3. For any new chemical entity in the Oral Anti-Emetics: Δ-9-THC Derivatives require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) dronabinol Non Preferred Agent (s) Cesamet® Marinol®
Oral Anti-Emetics: Δ-9-THC Derivatives Clinical Criteria Δ-9-THC Derivatives will be approved if one of the following is true: • Diagnosis of nausea and vomiting associated with cancer chemotherapy AFTER failure to respond adequately to at least ONE other anti-emetic therapy; OR • Diagnosis of anorexia associated with weight loss in patients with AIDS or cancer (dronabinol ONLY).	Δ-9-THC Derivatives will be approved if one of the following is true: • Diagnosis of nausea and vomiting associated with cancer chemotherapy AFTER failure to respond adequately to at least ONE other anti-emetic therapy; OR • Diagnosis of anorexia associated with weight loss in patients with AIDS or cancer (dronabinol ONLY).

Description of Recommendation	Final Decision (s)
Anti-Emetics: Other 1. DMS to select preferred agent (s) based on economic evaluation; however at least four unique chemical entities should be preferred. Metoclopramide, promethazine and prochlorperazine should be among the preferred agents. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Anti-Emetics: Other class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) meclizine metoclopramide prochlorperazine promethazine (all except 50 mg suppositories) Transderm-Scop® trimethobenzamide Non Preferred Agent (s) Antivert® Compazine® Compro® Diclegis® Metozolv® ODT Phenadoz® Phenergan® promethazine (50 mg suppositories) Reglan® Tigan®
Doxylamine/Pyridoxine (Diclegis®) Clinical Criteria Doxylamine/pyridoxine (Diclegis®) will be approved if ALL of the following criteria are met: • Patient is a female who is pregnant; AND • Patient has a diagnosis of nausea and vomiting of pregnancy; AND • Patient has tried and failed dietary and lifestyle modifications without adequate control of symptoms (per chart notes). Approval will be for 3 months at a time. Renewal will be allowed as long as the member is pregnant and continues to have a diagnosis of nausea and vomiting of pregnancy.	Doxylamine/pyridoxine (Diclegis®) will be approved if ALL of the following criteria are met: • Patient is a female who is pregnant; AND • Patient has a diagnosis of nausea and vomiting of pregnancy; AND • Patient has tried and failed dietary and lifestyle modifications without adequate control of symptoms (per chart notes). Approval will be for 3 months at a time. Renewal will be allowed as long as the member is pregnant and continues to have a diagnosis of nausea and vomiting of pregnancy.

Description of Recommendation	Final Decision (s)
Antispasmodics/Anticholinergics 1. DMS to select preferred agent (s) based on economic evaluation. However, at least one formulation of dicyclomine, glycopyrrolate, hyoscyamine, and methscopolamine 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 Antispasmodics / Anticholinergics class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) dicyclomine glycopyrrolate hyoscyamine methscopolamine propantheline Non Preferred Agent (s) Anaspaz® Bentyl® Cantil® chlordiazepoxide/clidinium Cuvposa® Donnatal® Glycate® Hyosyne® Levbid® Levsin® Librax® Oscimin SR® Pamine® Pamine Forte® Robinul® Robinul Forte®

Description of Recommendation	Final Decision (s)
Ulcerative Colitis Agents 1. DMS to select preferred agent (s) based upon economic evaluation; however, at least three unique chemical entities should be preferred. At least one oral mesalamine product as well as a mesalamine suppository and enema should be among the preferred products. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Ulcerative Colitis Agents class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) Apriso™ balsalazide Canasa® Delzicol® mesalamine enemas/suppositories sulfasalazine sulfasalazine EC Non Preferred Agent (s) Asacol® HD Azulfidine® Azulfidine EN-tabs® Colazal® Dipentum® Giazo Lialda™ mesalamine rectal kit Pentasa® Rowasa® sfRowasa® Uceris®
Antidiarrheals 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 will require Prior Authorization. 3. For any new chemical entity in the Antidiarrheals class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) diphenoxylate with atropine loperamide Non Preferred Agent (s) Fulyzaq® Lomotil® Motofen® opium paregoric

Description of Recommendation	Final Decision (s)
Crofelemer (Fulyzaq®) Clinical Criteria Approval of crofelemer will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Patient has been diagnosed with human immunodeficiency virus; AND o Patient is experiencing diarrhea; AND o Active infection has been ruled out via fecal collection and microbiologic culture; AND o Patient has tried and failed two preferred antidiarrheals. • For continuation of treatment, approve for one year if ALL of the following are true: o Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; AND o Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy.	Approval of crofelemer will be granted as described below. • For initial treatment, approve for 6 months if ALL of the following are true: o Patient has been diagnosed with human immunodeficiency virus; AND o Patient is experiencing diarrhea; AND o Active infection has been ruled out via fecal collection and microbiologic culture; AND o Patient has tried and failed two preferred antidiarrheals. • For continuation of treatment, approve for one year if ALL of the following are true: o Documented reduction in the frequency and quantity of liquid stool volume for the previous 6 months; AND o Documented follow-up with patient that includes re-culture for microbiologic agents if breakthrough diarrhea occurs while on crofelemer therapy.

Description of Recommendation	Final Decision (s)
Laxatives and Cathartics 1. DMS to select preferred agent (s) based on economic evaluation; however, at least two unique chemical entities should be preferred. The preferred products should include lactulose, polyethylene glycol, and one agent used for bowel evacuation or colon cleansing. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. For any new chemical entity in the Laxatives and Cathartics class, require a PA until reviewed by the P&T Advisory Committee.	Selected Preferred Agent (s) lactulose solution PEG-3350/electrolytes solution for reconstitution PEG 3350 powder Non Preferred Agent (s) Colyte® with flavor packets Constulose® Enulose® Entereg® GaviLyte-C® GaviLyte-G® GaviLyte-N® Generlac® GlycoLax® Golytely® powder pack/solution for reconstitution Halflytely-Bisacodyl Bowel Kit® Kristalose® packet Miralax® Powder Moviprep® Nulytely® with Flavor Packs solution for reconstitution OCL® Solution Osmoprep® Tablets PEG-3350/Flavor Packs Solution for Reconstitution PEG 3350 Powder Pack Prepopik™ Powder Pack Relistor® Suclear™ Suprep® TriLyte® Visicol®
Methylnaltrexone (Relistor®) Clinical Criteria Relistor® will be approved if all of the following criteria are met: • Diagnosis of opioid-induced constipation; AND • Patient has chronic pain; AND • Trial and failure (unless contraindicated or intolerant to) of an agent in each of the following drug classes: o Stool softening agent; AND o Peristalsis-inducing agent.	Relistor® will be approved if all of the following criteria are met: • Diagnosis of opioid-induced constipation; AND • Patient has chronic pain; AND • Trial and failure of (unless contraindicated or intolerant to) an agent in each of the following drug classes: o Stool softening agent; AND o Peristalsis-inducing agent.