Partnership HealthPlan of California: New and Revised Criteria, 2nd Quarter P & T 2016

Effective 7/01/2016

Generic substitution required when there is an FDA approved generic equivalent; additional criteria apply for brand name requests per PHC Policy MPRP4033.

HEADING	Drug/PA Group	Products Included in Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restriction	Prescriber Restriction	Coverage Duration	Other Criteria Requirements
DEFINITION	For PHC Internal use, used for grouping drugs with like criteria.	Drugs covered by the same TAR criteria. Trade names, strengths, dosage forms are for example only. Criteria apply to the active ingredient entity, unless separate criteria exist for different strengths/forms of same drug.	Indications for which PHC will consider prior authorization based on the stated criteria. Other uses may require additional documentation of safety, efficacy & medical necessity.	Specified reasons for denial (if any), other than not meeting criteria requirements.	Documents to be submitted with the TAR for clinical review. Absence of these documents will result in delay or denial of the request.	Any age limit or CCS screening associated with the drug.	Prescriber specialty requirement for TAR consideration, if any.	The maximum duration of TAR approval before renewal is required, when all criteria are met. Less than the maximum may be authorized when additional clinical information is required.	Other criteria and notations not included elsewhere.

- **This page is for general information only, to assist with interpretation of the TAR/PA criteria.**
- **Please review the information above if you are unfamiliar with this criteria format.**
- **New & revised criteria begin on the next page.**

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Contents:

Brand/Trade names are shown for reference purposes only. Criteria apply to the generic product when a generic equivalent has been approved by the FDA. Additional criteria apply to brand name requests (when a generic is available), per PHC Policy #MPRP4033.

Darifenacin (Enablex)
Solifenacin (Vesicare)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Additional Criteria
OAB EXTENDED RELEASE AGENTS	For the treatment of an overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge- related urinary incontinence.	None		Not Indicated for pediatric use.	None	Up to 12 months	Limited to members who have had an adequate trial (minimum 30 days) of preferred non-formulary fesoterodine (Toviaz) AND at least 2 of the following: Oxybutynin ER tablets, Tolterodine ER tablets* &/or Trospium ER tablets*. *Step therapy requirements for formulary alternatives: Tolterodine ER and trospium ER have a STEP therapy requirement for trial of oxybutynin ER tablets within the last 60 days.

Fesoterodine (Toviaz)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Additional Criteria
OAB EXTENDED RELEASE PREFERRED AGENTS	For the treatment of overactive bladder (OAB) with symptoms of urinary frequency, urinary urgency, or urge-related urinary incontinence.	None		Not indicated for pediatric use.	None	Up to 12 months	PHC's preferred non-formulary agent. Limited to members who have had an adequate trial (minimum 30 days) of at least 2 of the following: Oxybutynin ER tablets Tolterodine ER tablets*, Trospium ER tablets* *Step therapy requirements for formulary alternatives: Tolterodine ER and trospium ER have a STEP therapy requirement for trial of oxybutynin ER tablets within the last 60 days.

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Mirabegron (Myrbetriq)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Additional Criteria
BETA-3 ADRENERGIC RECEPTOR AGONIST	For the treatment of patients with overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.	None	Clinic notes documenting a specific contraindication to anticholinergics or previous treatments tried and failed.	Safety and effectiveness have not been established in pediatrics.	None	Up to 12 months	Limited to members with: Documented contraindication to anticholinergics (e.g., severely decreased GI motility conditions, uncontrolled narrow-angle glaucoma). *-or-* Adequate trial (minimum 30 days) of preferred non-formulary fesoterodine (Toviaz) AND at least 2 of the following: Oxybutynin ER tablets, Tolterodine ER tablets*, &/or Trospium ER tablets* *Step therapy requirements for formulary alternatives: Tolterodine ER and trospium ER have a STEP therapy requirement for trial of oxybutynin ER tablets within the last 60 days.

Oxybutynin topical gel (Gelnique)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Additional Criteria
OAB TOPICAL AGENTS	For the treatment of overactive bladder with symptoms of urge urinary incontinence, urgenc y, and frequency.	None	Clinic notes documenting the medical necessity of a non-oral route of administration and evaluation/nature of failure of OTC transdermal oxybutynin patch.	Safety and effectiveness have not been established in pediatrics.	None	Up to 12 months	Minimum 30 day trial with formulary OTC oxybutynin patch is required.

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Pitavastatin (Livalo)
Fluvastatin IR, XR (Lescol, Lescol XR)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
LIVALO & LESCOL	For the treatment of hyperlipemias and to reduce ASCVD risk in at-risk individuals; indicated as an adjunct to lifestyle modifications.		New Starts: TAR should include attachments which document the need for moderate intensity statin therapy, such as: 10-year ASCVD risk score is helpful but not required Specific risk factors if applicable (HTN, DM, Family Hx, hx CV events, smoking status, etc) If request is based on a specific LDL-C goal/ %reduction, provide baseline (untreated) LDL-C and LDL-C level on current treatment. Nature of failure of current regimen and other regimens tried & failed. Nature of failure of current regimen and other regimens tried & failed.	Pitavastatin: For adults (not FDA approved for pediatric use). Fluvastatin: Not FDA approved for pediatric use but has been evaluated in open-label, non-controlled trials in ages 9-16.	None	12 months per TAR approval	New Starts: For members requiring moderate intensity statin treatment (requesting Pitavastatin 2-4mg/day or fluvastatin 40 to 80mg/day), approval requires prior adequate use of formulary moderate-intensity statin regimens, and continued use of such is contraindicated due to an adverse reaction or drug interaction which is drug-specific not also associated with the requested product. Adequate trial consists of prior use of at least 3 formulary statins, one of which must be Atorvastatin, in the following minimum doses to achieve moderate-intensity effect: Atorvastatin 20mg, Simvastatin 40mg, Pravastatin 80mg, Lovastatin 40mg. Low-intensity (requesting Pitavastatin 1mg or fluvastatin 20mg): Same as the above, with adequate trial of formulary being trial of at least 3 formulary alternatives, at any dose. Note: Pitavastatin & Fluvastatin are not recommended for high-intensity treatment.

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Rosuvastatin (Crestor)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
CRESTOR	For the treatment of hyperlipemias and to reduce ASCVD risk in at-risk individuals; indicated as an adjunct to lifestyle modifications.		New Starts: Documentation from the clinical record indicating why atorvastatin cannot be used. In addition: TAR should include attachments which indicate the rationale for the requested statin therapy intensity level (moderate intensity at 5-10mg/day or high intensity at 20-40mg/day.) Examples of documentation to support the requested rosuvastatin intensity dosing: o 10-year ASCVD risk score is helpful but not required o Specific risk factors if applicable (HTN, DM, Family Hx, hx CV events, smoking status, etc) o If request is based on a specific LDL-C goal/% reduction, provide baseline (untreated) LDL-C and LDL-C level on current treatment. o For cases in which multiple formulary agents at maximal tolerated doses have not had an adequate response, an evaluation of member's level of medication & dietary adherence is suggested.	8 years and older	None	12 months per TAR approval	New Starts: For members requiring moderate-intensity statin treatment (requesting rosuvastatin 5-10mg/day), the use of rosuvastatin requires adequate prior use of formulary moderate-intensity statin regimens, and continued use of such is contraindicated due to an adverse reaction or drug interaction which is drug-specific not also associated with rosuvastatin. Adequate trial consists of prior use of at least 2 formulary statins, one of which must me Atorvastatin, in the following dosing to achieve moderate-intensity therapeutic affect: Atorvastatin 20mg, Simvastatin 40mg, Pravastatin 80mg, Lovastatin 40mg. Half-tablet substitution is required. For members requiring high-intensity statin treatment (requesting rosuvastatin 20-40mg/day), use is limited to those members with adequate prior use of a formulary high-intensity statin regimen, and continued use of such is contraindicated due to an adverse reaction or drug interaction which is drug-specific & not also associated with rosuvastatin. Adequate trial consists of Atorvastatin at high intensity dosing, 80mg/day. Half-tablet substitution is required for 20mg requests.

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Canagliflozin (Invokana)
Canagliflozin/metformin (Invokamet)
Dapagliflozin (Farxiga)
Dapagliflozin/metformin (Xigduo XR)
Empagliflozin/metformin (Synjardy)
Empagliflozin/linagliptin (Glyxambi)
Empagliflozin (Jardiance)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
SODIUM GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS	**Adults with type 2 diabetes mellitus. SGLT-2i**	**1. Type 1 diabetes mellitus. 2. Severe renal impairment, end-stage renal disease, or dialysis**	**Submit the following with the TAR: Completed TAR Supplemental Form HgA1C lab report, drawn within the last 90 days. Note: Exception—the above is not required if treatment is prescribed by a board certified endocrinologist**	**18 years or older**	**Criteria waived for board certified endocrinologist**	**12 months per TAR approval**	**New Starts: Limited to members with HgA1C = 7.5 – 9.0 within the last 90 days AND one of the following: (1) If HgA1C is 7.5 to 8.0, must have had a concurrent, 3 consecutive month trial or contraindication to two oral agents at maximal tolerated doses, one of which is metformin (formulary oral agents: sulfonylurea, meglitinide, thiazolidinedione, A- glucosidase inhibitor; formulary STEP: DPP-4 inhibitor) *-or-* (2) If HgA1C is 8.0 to 9.0, must have had a documented Trial or contraindication to both metformin and a long-acting insulin, at maximally tolerated doses.**

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Dulaglutide (Trulicity)
Liraglutide (Victoza)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
GLP-1 RECEPTOR AGONISTS, GROUP 1	For the treatment of adult type 2 diabetes mellitus in combination with diet and exercise	Type 1 diabetes mellitus. History of or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2.	Submit the following with the TAR: Completed TAR Supplemental Form HgA1C lab report, drawn within the last 90 days. Current BMI Note: Exception—the above is not required if treatment is prescribed by a board certified endocrinologist	18 years or older.	Criteria waived for board certified endocrinologist	12 months per TAR approval	New Starts: Limited to members with ALL of the following: (1) HgA1C = 8.0 -10.0 within the last 90 days. (2) Concurrent, 3 consecutive month trial or contraindication to two oral agents at maximal tolerated doses, one of which is metformin (formulary oral agents: sulfonylurea, meglitinide, thiazolidinedione, A-glucosidase inhibitor; formulary STEP: DPP-4 inhibitor). (3) BMI greater than 35 with failure to conventional weight loss therapy. Member continues to follow diet and exercise plan, preferably within a diabetic education program.

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Albiglutide (Tanzeum)
Exenatide (Byetta)
Exenatide ER (Bydureon)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
GLP-1 RECEPTOR AGONISTS, GROUP 2	For the treatment of adult type 2 diabetes mellitus in combination with diet and exercise	Type 1 diabetes mellitus. History of or family history of medullary thyroid carcinoma or multiple endocrine neoplasia syndrome type 2	Submit the following with the TAR: Completed TAR Supplemental Form HgA1C lab report, drawn with in the last 90 days. Current BMI Note: Exception—the above is not required if treatment is prescribed by a board certified endocrinologist	18 years or older	Criteria waived for board certified endocrinologist	12 months per TAR approval	New Starts: Limited to members with ALL of the following: (1) HgA1C = 8.0 -10.0 within the last 90 days. (2) Concurrent, 3 consecutive month trial or contraindication to two oral agents at maximal tolerated doses, one of which is metformin (formulary oral agents: sulfonylurea, meglitinide, thiazolidinedione, A-glucosidase inhibitor; formulary STEP: DPP-4 inhibitor). (3) BMI greater than 35 with failure to conventional weight loss therapy. (4) Member continues to follow diet and exercise plan, preferably within a diabetic education program. (5) Adequate trial of preferred non-formulary GLP-1 agonists (dulaglutide & liraglutide) and is unable to continue for clinical reasons (details to be included on the TAR Supplemental Form).

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Insulin Degludec pen 100 & 200 U/ml (Tresiba Flex Touch)
Insulin glargine 300 U/ml (Toujeo)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
LONG-ACTING BASAL INSULINS	For treatment of adult type 1 and type 2 diabetes mellitus	Not recommended for the treatment of diabetic ketoacidosis	Submit the following with the TAR: Completed TAR Supplemental Form FBS records for the past 30 days If member is experiencing hypoglycemia: Clinic notes which include assessment & management of hypoglycemic events.	18 and older (Safety & Efficacy not established in <18 yo) Ages 0-20: CCS eligible drug, screening/referral processes apply.	Criteria waived for Board certified endocrinologist	12 months per TAR approval	Limited to members who meet either: FBG values from past 30 days document member is not at ADA goal (70-130) after adequate trials of Lantus or Levemir (exceeding 1 unit/kg/day total daily dose) and claim history shows member has adhered to insulin regimen. *-or-* Documented episodes of nocturnal hypoglycemia or recurrent, unpredictable, or severe day time hypoglycemia with wide fluctuation in blood glucose readings not resolving with adjustment of insulin dose, diet, or exercise. Note: Levemir is not associated with burning & stinging at injection site.

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Teriparatide 600 mcg/2.4 mL injection solution (Forteo)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
ENDOCRINE BONE FORMATION STIMULATING AGENTS-PARATHYROID HORMONE ANALOG	Treatment of osteoporosis (men, postmenopausal women, and glucocorticoid induced)	Prophylaxis use Metabolic bone disease(s) other than osteoporosis Anyone with increased baseline risk for osteosarcoma (Paget's disease, unexplained elevated Alkaline Phosphatase, open epiphyses, prior external beam or implant radiation therapy involving skeleton)	Include with TAR submission: Clinic notes detailing osteoporotic fracture history &/or low trauma fractures BMD T-Score Documentation of inadequate response or contraindications to alternative treatments, from the medical record.	≥ 18 years old Safety and effectiveness have not been established in children	None	Up to 6 months per TAR approval	Max day-supply per fill: 28 days. Treatment beyond 24 months not recommended due to increased risk of osteosarcoma. Limited to members with documented history of adequate trial and failure/intolerance/ contraindication to alternative treatments* AND have documentation of one of the following: 1. Osteoporotic fracture(s), 2. Two or more risk factors for osteoporotic fracture (eg., multiple recent low trauma fractures, T-Score ≤-2.5 or chronic corticosteroid use) 3. Severe Osteoporosis defined as: i. Absence of fractures with T-Score ≤ -3.5 or ii. T-Score ≤ -2.5 with history of fragility fracture *For (a) and (b), trial and failure of formulary alendronate and one other oral bisphosphonate; also failure with raloxifene (Evista; women only), calcitonin nasal spray (Miacalcin), zoledronic acid (Reclast) *and* denosumab (Prolia). For (c)/severe disease, must have been initially treated with oral bisphosphonates but unable to tolerate them.

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Calcitonin 200U/ml injection (Miacalcin)
Calcitonin Nasal solution 200U/act (Miacalcin and Fortical)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
ENDOCRINE CALCITONINS	Adjunctive therapy for hypercalcemia. Treatment of symptomatic Paget disease of bone (osteitis deformans) in patients who are nonresponsive or intolerant to alternative therapy. Treatment of osteoporosis in women more than 5 years postmenopause	None	TAR should include the following from the medical record: Osteoporosis: • Specific diagnosis • T-Score • History of illness • Menopausal status • If post-menopausal, # of years post-menopause. • Risk factors (eg, recent low- trauma fractures, T-Score <-2.5, chronic corticosteroid use) Paget's Disease: • Documentation of disease history & current disease activity • Most recent Alkaline Phosphatase level Hypercalcemia: • Current calcium lab level All: • Documentation of reasons why alternative treatments cannot be used, from the medical record.	≥ 18 years old Safety and effectiveness have not been established in children.	None	6 months per TAR approval	Osteoporosis: • Limited to members who have a documented history of osteoporotic fracture(s) or have at least 2 fracture risk factors AND • Have had failures of adequate therapy with all other available agents: calcitonin salmon nasal spray, oral bisphosphonates (Alendronate, Ibandronate, pamidronate and risedronate), injectable bisphosphonate (Ibandronate/Boniva), raloxifene (Evista), zoledronic acid (Reclast) and denosumab (Prolia) Paget's Disease: • Limited to members who have had adequate trials of oral bisphosphonates (Alendronate and risedronate, minimum 60 day trial each, 30mg/day) and zoledronic acid (5mg single-dose infusion) Hypercalcemia, acute: • Limited to members who are symptomatic and have calcium >14mg/dL Hypercalcemia, long-term management: • Limited to members who have had trial and failure or intolerance to bisphosphonates, zoledronic acid, and denosumab.

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Nisoldipine (Sular)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
DIHYDROPYRIDINE (DHP) CALCIUM CHANNEL BLOCKERS, LONG ACTING	For the treatment of hypertension	None	Supporting clinical notes from the patient's medical record as to why formulary calcium channel blockers cannot be used (eg, documented allergic reactions, doses used & response to treatment, BP measures, etc).	18 years and older. Safety and efficacy have not been established.	None	12 months per TAR approval	New Starts: Limited to members who have had documented trial & failure of formulary amlodipine, nifedipine, and felodipine. Ages < 20 years: Subject to CCS review/referral.

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Lumacaftor/Ivacaftor (ORKAMBI)

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
CYSTIC FIBROSIS TRANSMEMBRANE CONDUCTANCE REGULATOR (CFTR) POTENTIATORS	For the treatment of cystic fibrosis (CF) in patients who are homozygous for the F508del mutation in the CFTR gene	Heterozygous F508del mutation Any other GFTR gene mutation Concurrent use of moderate or strong CYP3A inhibitors Concurrent use with Ivacaftor (Kalydeco)	**INITIAL REQUEST** • Copy of the FDA-cleared CF mutation analysis test result must be provided to support presence of homozygous F508del mutation (mutation testing indicates individual has two copies of the F508del mutation). • Baseline or current (within 60 days of request) liver function tests (AST/ALT) and bilirubin levels • Baseline forced expiratory volume in one second (FEV1) : • Ages 12-20, FEV </=90 & 2 recent FEV1 measures. • Ages >/=21, FEV </= 80 & 2 recent FEV1 measures. • Chart notes to document: 1. Number of and type of pulmonary exacerbations, as defined by need for intravenous antibiotics 2. Hospitalization and ER visits within previous 12 months 3. Changes in medications and broncho- therapy in previous 12 months Request outside of criteria will be reviewed on a case by case basis. **RENEWAL:** • LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin • Clinic notes documenting improvement in patient symptoms including stable or improved lung function.	12 years and older. Infants and Children < 12 years: Safety and efficacy have not been established. Ages 0-20: subject to PHC CCS screening and referral for CCS coverage of CCS eligible condition.	Prescriber is a CF specialist or pulmonologist	TBD	CCS Carve-In Counties: Submission of CCS SAR Notice of action (approval) with TAR, OR submit all documentation required to meet PHC Criteria if no LUMACAFTOR-IVACATOR SAR exits. • Diagnosis of cystic fibrosis (CF) • Lab results confirming patient is homozygous for the F508del mutation in the CFTR gene • Prescribed by or in consultation with a prescriber who specializes in treating CF patients. • Baseline or current (within 60 days of request) liver function tests (AST/ALT) and bilirubin levels RENEWAL: • Response to therapy is documented by prescriber (e.g., improved FEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care). • LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function. • Adherent to medical regimen LFTs/bilirubin: Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter with adjustment in dosing dependent on severity of liver function.

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Daclatasvir (Daklinza) **Elbasvir/Grazoprevir (Zepatier)** **Sofosbuvir (Sovaldi)**
Ribavirin (Copegus) **Simeprevir (Olysio)** **Ledipasvir/Sofosbuvir (Harvoni)**
Ombitasvir/Paritaprevir/Ritonavir (Technivie) **Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira Pak)**

Drug Group	Covered Uses	Exclusion Criteria	Required Medical Documentation	Age Restrictions	Prescriber Restrictions	Coverage Duration	Other
HEP C TREATMENT 2016	For treatment of chronic Hepatitis-C Virus (HCV) with fibrosis stage F2 or greater. For treatment of chronic HCV with fibrosis stage less than F2 in the presence of specific comorbities or circumstances including: • Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (vasculitis) or kidney disease (e.g. proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis). • Hepatocellular Carcinoma (HCC) with a life expectancy of greater than 12 months. • Pre- and post-liver or other solid organ transplant. • HIV – 1 co-infection. • Hepatitis B co-infection. • Other co-existing liver disease (e.g. non-alcoholic steatohepatitis). • Insulin resistant type 2 diabetes.	Failure to comply with treatment regimen (e.g. multiple missed doses), medication loss, missed appointment, missed lab data sets &/or non-compliance with case management may result in revocation of treatment authorization.	Specifics are listed on PHC HCV TAR supplemental form. A completed TAR Supplemental Form must be submitted for initial TAR requests. Most recent original data reports (including reference ranges) for the following: (1) HCV genotype & viral load. (2) Chemistry which includes AST, ALT, Total Bilirubin, Albumin. (3) CBC with Platelets. (4) If cirrhosis, include INR and CTP score. (5) Evidence of fibrosis stage / Metavir score (FibroSure/FibroTest, FibroScan, biopsy, ultrasound, biochemical profile, evidence of portal HTN, varices, ascites, encephalopathy).	18 years and older.	Specialist in the area of Gastroenterology, Hepatology, Infectious Disease, HIV OR non-specialist with documentation of adequate training & experience in the treatment of HCV (e.g. Project ECHO).	Dependent upon genotype, prior treatment (if any), cirrhosis status, regimen and response.	Diplomat Specialty Pharmacy required. 14-day dispensing limitation per fill. Prescriber has considered patient readiness, transplant status, pregnancy risks, renal function, life expectancy, case management, patient responsibilities and prescriber's experience (the latter required one-time for non- specialist prescribers) as indicated in the HCV TAR Supplement Form. In-Therapy HCV Viral Load (VL) testing require: (1) Baseline VL or start of treatment VL if baseline older than 12 months. (3) 4-wk. (4) 6-wk if detectable at 4 wks for 12 wk regimen OR 12-wk if detectable at 4 wks for 16 wk regimen. (5) 12-wk if on regimen lasting beyond 16 weeks. Requests for non-AASLD regimens: current medical literature supporting the regimen should be submitted.

ADDITIONAL CRITERIA BELOW

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	• **Men who have sex with men with high risk practices,** • **Porphyria cutanea tarda.** • **Active injection drug user.** • **Long-term hemodialysis.** • **Woman of child-bearing age (fertile) who wish to get pregnant.** • **HCV-infected health care worker who performs exposure-prone procedures.** • **Debilitating fatigue impacting the quality of life (e.g. secondary to extra-hepatic manifestations and/or liver disease).**		**If applicable:** (6) **Request for Zepatier for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA Genotype 1 NS5A Drug Resistance Assay result.** (7) **Request for Olysio for genotype 1a, mixed 1a/b, or indeterminate 1 infection will require submission of HCV RNA NS3 Drug Resistance (Q80k polymorphism) Assay result.** (8) **Documentation of pregnancy prevention while on Ribavirin therapy.** (9) **Documentation of Interferon and/or Ribavirin intolerance or other ineligible rationale.**				**PHC Preferred Regimens:** **See HCV treatment matrix on PHC website for all preferred regimens.** **For example: GT1a, tx-naive, no cirrhosis -- Although Zepatier and Viekira Pak are indicated for 12-week duration of treatment, Zepatier is preferred & use of Viekira Pak would require documentation of contraindication/intolerance with Zepatier.** **Generic ribavirin 200mg capsules / tablets preferred - requests for RibaPak, Moderiba dose pack, or other brand requests require additional justification per PHC brand policy.**