MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

April 26, 2017

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: LYNNE FOSTER, CHIEF OF DIVISION COMPLIANCE

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 – PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 1200 – Prescribed Drugs, include adding clarifying language to Continuity of Care, Emergency Supply of Medication, override codes for Pro-DUR functions, Medical/Surgical, Specialty and Psychiatric Hospitals and outpatient pharmaceuticals. Policy was added for Dispensing Practitioners. Clarifying policy language was added to drugs administered in an outpatient setting, a hospital-based outpatient clinic, an End Stage Renal Disease (ESRD) facility, an emergency room, an ambulatory surgical center, an outpatient hospice and to clinics paid by encounter. Deleted language under Coordination of Benefits, non-participating Health Maintenance Organization (HMO) Providers, the Pharmacy Billing Process and Intravenous (IV) Therapy. Clarifying language was added under the State Maximum Allowable Cost (SMAC). The language under Prior Authorization (PA) Procedures was revised. Under Long Term Care, the dispensing fee was updated.

Revisions to Appendix A were made to reflect approved actions by the Drug Use Review (DUR) Board at the July 28, 2016 and the October 27, 2016 meetings.

On July 28, 2016, new prior authorization criteria was approved for gonadotropin-releasing hormone analogs (Lupron®) and drugs to treat Irritable-Bowel Syndrome. Prior authorization criteria was revised for antiasthmatic monoclonal antibodies (Xolair®). Prior authorization criteria removed for duloxetine (Cymbalta®).

On October 27, 2016, revised prior authorization criteria was approved for Hepatitis C direct-acting antivirals. New criteria was approved for initial prescriptions of long and short-acting opioids.

Throughout the chapter, grammar, punctuation and capitalization changes were made, duplications removed, acronyms used and standardized, and language reworded for clarity. Renumbering and re-arranging of sections was necessary.

These changes are effective April 27, 2017.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 30876 Prescribed Drugs	MTL 26/15, 24/16, 01/17 Prescribed Drugs

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1(2)(a)(7)	**Coverage and Limitations**	Added "Antidepressant." Language now reads "Psychotropic, Antidepressant Medication" – "Continuity of Care." Added the language "and/or non-preferred antidepressant." Language now reads, "Recipients discharged from an institution on non-preferred psychotropic and/or non-preferred antidepressant medication(s)..."
1203.1(3)	**Coverage and Limitations**	Deleted "Nevada Medicaid Drug Rebate program" and replaced it with "The DHCFP…"
1203.1(7)(e)	**Coverage and Limitations**	Under Emergency supply of medication, added "An approved PA (if required) will be necessary to get additional medication."
1203.1(11)(a-h)	**Coverage and Limitations**	Under Dispensing Practitioners, added the requirements: current Certificate of Registration through the Nevada State Board of Pharmacy; enrollment with Nevada Medicaid as a Provider Type 28; a separate NPI exclusively utilized for pharmacy services; offices must be located in the State of Nevada, all prior authorization criteria and quantity limits apply; only Provider Type 28 can be reimbursed for a dispensing fee, all claims must be submitted in the NCDCP format and compliance with all Board of Pharmacy statutes and regulations.
1203.1A(2)(a)(1)	**Provider Responsibility**	Under Utilization Control, deleted the language "and paper Uniform Claim Form (UCF) claims."
1203.1A(2)(a)(4)	**Provider Responsibility**	Deleted "prior authorizations" and replaced it with "override codes."
1203.1B(1)(a)	**Service Delivery Model**	Deleted "and" and added the language "…and free-standing inpatient hospice facilities."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
1203.1B(1)(a)(1)	**Service Delivery Model**	Added clarifying language, "Legend (prescription)…" Added clarifying language, "Legend pharmaceuticals are billed separately…" Added clarifying language "Non-legend (over the counter) pharmaceuticals are not separately reimbursable by the DHCFP."
1203.1B(1)(b)(3)	**Service Delivery Model**	Added language for hospice services in NFs, all drugs related to the terminal illness and palliative, symptom relief are to be covered by the hospice and will not be reimbursed by the DHCFP. Referenced MSM Chapter 3200, Hospice.
1203.1B(2)(a)	**Service Delivery Model**	Revised language for clarity. It now reads "Covered outpatient drugs (COD(s)) are reimbursed separately from medical services in the following settings, in accordance with Section 1927 of the Social Security Act (SSA)."
1203.1B(2)(a)(2)(a)	**Service Delivery Model**	Added the language that disposable supplies are billed separately with a 33 Provider Type number.
1203.1B(2)(a)(2)(b)	**Service Delivery Model**	Added the language referencing the Pharmacy Billing Manual.
1203.1B(2)(a)(3)	**Service Delivery Model**	Revised language regarding physician administered drugs. The language now reads "COD(s) administered in an outpatient setting, such as a physician's office (NVPAD)."
1203.1B(2)(a)(3)(a)	**Service Delivery Model**	Revised the language, it now reads "COD(s) are billed utilizing the appropriate National Drug Code (NDC) and NDC quantity (billed through MMIS).
1203.1B(2)(a)(4)	**Service Delivery Model**	Under hospital based outpatient clinics, deleted the language "…all pharmacy charged are billed separately."
1203.1B(2)(a)(4)(a)	**Service Delivery Model**	Revised the language, it now reads "COD(s) are billed utilizing the appropriate NDC and NDC quantity (billed through MMIS)."
1203.1B(2)(a)(5)(a,c)	**Service Delivery Model**	Under End Stage Renal Disease (ESRD) Facilities, revised the language, it now reads "Any COD(s) not

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		included in the Prospective Payment System (PPS) Rate are billed using the…" Deleted "Drugs" and replaced it with "COD(s)."
1203.1B(2)(a)(6)(a)	**Service Delivery Model**	Under Emergency Rooms, revised the language, it now reads "COD(s) are billed utilizing the appropriate NDC and NDC quantity (billed through MMIS)."
1203.1B(2)(b)	**Service Delivery Model**	Revised the language, it now reads "CODs are not reimbursed separately in the following settings, …"
1203.1B(2)(b)(1)	**Service Delivery Model**	Deleted "Hospital-Based Ambulatory Infusion Centers." It now reads "Ambulatory Surgical Centers (ASC), COD(s) are included in the facility rate and may not be billed separately." Language regarding Emergency Rooms has been moved to 1203.1B(2)(6).
1203.1B(2)(b)(2)	**Service Delivery Model**	Added language regarding outpatient clinics that are paid by encounter, cannot bill separately for COD(s) when drugs are included in their encounter.
1203.1B(2)(b)(3)	**Service Delivery Model**	Added language regarding outpatient hospice, COD(s) related to the terminal illness and palliative, symptom relief are to be covered by the hospice and will not be reimbursed by the DHCFP. MSM Chapter 3200, Hospice referenced.
1203.1B(5)	**Service Delivery Model**	Coordination of Benefits (COB) language is being deleted as it is already found in Section 3.12 Coordination of Benefits in the Nevada Medicaid and Check Up Pharmacy Billing Manual.
1203.1B(6)	**Service Delivery Model**	Under Non-participating Health Maintenance Organization (HMO) Providers, this language is being deleted, as this language is found in MSM Chapter 100, Section 104(c-d) and Section 104.1.
1203.1B(7)	**Service Delivery Model**	Pharmacy Billing Process to be moved to the Nevada Medicaid and Check Up Pharmacy Billing Manual.
1203.1B(8)(a)(1-2)	**Service Delivery Model**	Under State Maximum Allowable Cost (SMAC), Fiscal Agent was deleted and replaced with QIO-like vendor.

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1203.1B(8)(b) (1&3)	**Service Delivery Model**	Language "Fiscal Agent" was deleted and replaced with "QIO-like vendor." Language "Fiscal Agent" was deleted and replaced with "QIO-like vendor."
1203.1C	**Authorization Procedures**	AUTHORIZATION PROCEDURES now reads PRIOR AUTHORIZATION (PA) PROCEDURES. Opening paragraph deleted.
1203.1C(1)(a-d)	**Authorization Procedures**	Deleted language as the information is obsolete.
1203.1C(1)	**Authorization Procedures**	Revised language, it now reads "via phone, fax or via the internet…"
1203.1C(2-7)	**Authorization Procedures**	Revised the language to add PA requests must be submitted on the appropriate form, added the web address for the PA forms, LTC drugs are subject to PA requirements, the QIO-like vendor will process the request within 24 hours of its receipt, the requesting practitioner will be advised of the PA status, pended PA requests will deny if the practitioner does not respond within three working days, the approved PA will be entered in the POS system, and the QIO-like vendor will send all denial of service letters, and added reference to MSM Chapter 3100 - Hearings. Revised the reference to the Nevada Medicaid and Check-Up Pharmacy Billing Manual.
1203.1C(2)	**Prior Authorization Procedures**	Under Prior Authorization Protocols, this information has been revised and is now found in Section 1203.1C(2-7).
1203.2	**Intravenous (IV) Therapy Provider Type 37**	The language "PROVIDER TYPE 37" has been deleted, and the opening paragraph has been deleted. New language referencing the Nevada Medicaid Check-Up Pharmacy Billing Manual has been added.
1203.2(a)	**Intravenous (IV) Therapy Provider Type 37**	Under Billing Guidelines, the language regarding a 37 Provider Number is required, and paper multi-ingredient UCF has been deleted. The word "performed" is being replaced with "processed."

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		Language regarding billing units is being moved to the Pharmacy Billing Manual. Language regarding Dispensing Fees is being moved under Section 1203.2(b)(1), Long Term Care (LTC). It is also found in the Pharmacy Billing Manual Section 3.22. Injectable Drugs.
1203.2(b)(1)	**Intravenous (IV) Therapy Provider Type 37**	Under Long Term Care (LTC), language regarding Dispensing Fees is updated and moved from Section 1203.2(b).
1203.2(b)(1) (a&b)	**Intravenous (IV) Therapy Provider Type 37**	Language revised for clarity, language now reads "…heparin) and supplies associated with IV therapy, enteral nutrition and TPN…" Language regarding which items can be billed separately has been deleted. It now reads "Refer to MSM Chapter 500 - Nursing Facilities for further information."
1203.2(c)	**Intravenous (IV) Therapy Provider Type 37**	Under Supplies, deleted language as it is found in Section 1203.1B(3) "Disposable Medical Supplies."
Appendix A(P)	**Monoclonal Antibody Agents**	Revised drug class, changed from Xolair® (Omalizumab) to Monoclonal Antibody Agents. The Last Reviewed was date updated to July 28, 2016. Language added "Xolair previously reviewed: July 20, 2014, April 23, 2015."
Appendix A(P) (1)(a)(1)	**Monoclonal Antibody Agents**	Criteria for Xolair® (Omalizumab) revised, the recipient will not use the requested drug in combination with other antiasthmatic monoclonal antibodies.
Appendix A(P) (1)(a)(2)	**Monoclonal Antibody Agents**	The language was revised, it now reads "All the following criteria must be met and documented for a diagnosis of moderate to severe asthma:"
Appendix A(P) (1)(a)(2)(a-f)	**Monoclonal Antibody Agents**	Language for 12 years of age or older revised for clarity. Moved the language regarding the prescriber must be a pulmonologist or allergist/immunologist, and the

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		recipient must have a positive skin or RAST test to b and c. Language was revised from "tried and failed or have a contraindication" to "had an inadequate response, adverse reaction or contraindication…"
Appendix A(P) (1)(a)(2)(g)	**Monoclonal Antibody Agents**	Added the language "…between 30 IU/mL and 700 IU/mL and…"
Appendix A(P) (1)(a)(2)(i)	**Monoclonal Antibody Agents**	Added the language "(see Table 1)."
Appendix A(P) (1)(a)(3)	**Monoclonal Antibody Agent**	The language was revised; it now reads "All the following criteria must be met for a diagnosis of chronic idiopathic urticaria (CIL)." Deleted language regarding must meet all of the following criteria.
Appendix A(P) (1)(a)(3)(a)	**Monoclonal Antibody Agent**	The language "of age" was added for clarity and consistency.
Appendix A(P) (1)(a)(3)(b)	**Monoclonal Antibody Agent**	Language was changed from "tried and failed or have a contraindication" to "had an inadequate response, adverse reaction or contraindication to two different oral second generation antihistamines; and…"
Appendix A(P) (1)(a)(3)(c)	**Monoclonal Antibody Agent**	Language was changed from "tried and failed or have a contraindication" to "had an inadequate response, adverse reaction or contraindication…"
Appendix A(P) (1)(a)(3)(d)	**Monoclonal Antibody Agent**	Language was added regarding documentation that a consultation was done by an allergist/immunologist, dermatologist or rheumatologist regarding the diagnosis and treatment recommendations.
Appendix A(P) (1)(a)(3)(e) (1&2)	**Monoclonal Antibody Agent**	Language was added regarding the requested dose: Initial therapy of 150 mg or 300 mg every four weeks with clinical rationale for starting at 300 mg every four weeks. Language was added for continuation of therapy: 150 mg or 300 mg every four weeks.

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Appendix A(P) (1)(b)(1)(a-g)	**Monoclonal Antibody Agent**	New language was added for Nucala® (mepolizumab) and Cinqair® (reslizumab). New language reads the recipient will not use the requested drug in combination with other antiasthmatic monoclonal antibodies; The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; for mepolizumab the recipient must be 12 years of age or older, for reslizumab 18 years of age or older; the prescriber must be a pulmonologist or allergist/immunologist; the recipient must be uncontrolled on current therapy including high dose corticosteroids and/or on a secondary asthma inhaler; vaccination status is documented; the requested dose is mepalozumab: 100 mg every four weeks; and reslizumab: 3mg/kg infusion every four weeks.
Appendix A(Z)	**Cymbalta**	All criteria for Cymbalta® (duloxetine) is being deleted and criteria for Opioids is been added.
	Opioids	The Therapeutic Class of Serotonin-Norepinephrine Reuptake Inhibitor (SNRI) is being replaced with Opioids.
	Opioids	The last reviewed date is being changed to October 27, 2016.
	Opioids	The disclaimer for prior authorization and quantity limitations is being changed from Cymbalta® to Opioids.
Appendix A(Z) (1)(a)(1-3)	**Opioids**	Added language for coverage without a Prior Authorization; initial prescriptions of seven days or less, for a total of 13 seven-day prescriptions, for 60 mg morphine equivalents of less per day.
Appendix A(Z) (1)(b)	**Opioids**	Added language that recipients currently on chronic opioid medications will not be subject to the seven-day requirement.
Appendix A(Z) (1)(c)(1)(a-d)	**Opioids**	Added criteria for exceeding the seven-day prescription limit, or to exceed the 60 mg morphine equivalents: the recipient has chronic pain or requires extended opioid therapy, is under the supervision of licensed prescriber, pain cannot be controlled through non-opioid therapy, the lowest effective dose is being requested and a pain contract is on file.

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Appendix A(Z) (1)(d)(1-6)	**Opioids**	Added exceptions to the policy: recipients with cancer/malignancy related pain; recipients who are post surgery with anticipated prolonged recovery, recipients receiving palliative care; or recipients in long-term care facilities, recipients receiving treatment for HIV/AIDS or prescriptions written by or in consultations with a pain specialist.
Appendix A(Z) (2)	**Opioids**	Prior Authorization Guidelines moved.
Appendix A(Z) (3)	**Opioids**	Added the reference to the CDC opioid guidelines.
Appendix A (UU)	**Hepatitis C direct-acting antivirals**	Updated the last reviewed date to July 28, 2016. Added previously reviewed date as January 28, 2016.
Appendix A (UU)(2)(b)(3)	**Hepatitis C direct-acting antivirals**	Deleted the language "has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) …"
Appendix A (UU)(2)(b)(4)	**Hepatitis C direct-acting antivirals**	Deleted all the language in Sections 4, a, and b.
Appendix A (UU)(2)(b)(4)(b)	**Hepatitis C direct-acting antivirals**	Added the word "Compensated" before "cirrhosis."
Appendix A (UU)(2)(c)(1) (a&b)	**Hepatitis C direct-acting antivirals**	Deleted numbers "5, 6," the language now reads "Genotype 4." Added the language for treatment naïve recipients: no cirrhosis and the requested duration is 12 weeks or compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.
Appendix A (UU)(2)(c)(2) (a&b&c)	**Hepatitis C direct-acting antivirals**	Added language for treatment experienced recipients: (failed peginterferon + ribavirin): no cirrhosis and the requested duration is 12 weeks; compensated cirrhosis (CTP class A), treated with ribavirin and the requested duration is 12 weeks; or compensated cirrhosis (CTP class A) documentation provided, the recipient is unable to take ribavirin and the requested duration is 24 weeks.

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Appendix A (UU)(2)(d)	**Hepatitis C direct-acting antivirals**	Added language "Genotype 5 and 6."
Appendix A (UU)(2)(d)(1)	**Hepatitis C direct-acting antivirals**	Deleted the all the language under Section 1.
Appendix A (UU)(2)(d)(2)	**Hepatitis C direct-acting antivirals**	Deleted the language "± an NS3 protease inhibitor…"
Appendix A (UU)(3)(b)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(3)(b)(2)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen." Deleted all the language under Section b and c.
Appendix A (UU)(4)(b)	**Hepatitis C direct-acting antivirals**	Deleted: "The recipient does not have cirrhosis."
Appendix A (UU)(4)(b)(1)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "The recipient is treatment-naïve and must meet one of the following:"
Appendix A (UU)(4)(b)(1)(a&b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or" Revised the language, it now reads "Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks."
Appendix A (UU)(4)(b)(2)	**Hepatitis C direct-acting antivirals**	Deleted the language under Section 2. Added language "…and must meet one of the following:"
Appendix A (UU)(4)(b)(2)(a&b)	**Hepatitis C direct-acting antivirals**	Revised the language, "No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks; or"

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		Revised the language, it now reads, "Compensated cirrhosis (CTP class A) will be treated with ribavirin and the requested duration is 12 weeks."
Appendix A (UU)(5)(a)(3)	**Hepatitis C direct-acting antivirals**	The language is revised it now reads: "90 mg (one tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer."
Appendix A (UU)(5)(b)(1)(a)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads. "…with Sovaldi and the requested duration…"
Appendix A (UU)(5)(b)(1)(b&c)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Sections b and c.
Appendix A (UU)(5)(b)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…Sovaldi + ribavirin, the requested duration is 24 weeks; and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(5)(b)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…Sovaldi, the requested duration is 24 weeks, documentation has been provided showing the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(5)(b)(2)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…Sovaldi and ribavirin, the requested duration is 24 weeks; and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(5)(b)(2)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…Sovaldi, the requested duration is 24 weeks, documentation is provided showing the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(5)(b)(3)	**Hepatitis C direct-acting antivirals**	Deleted the language: "…has had no prior treatment with an NS3 polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) …"
Appendix A (UU)(5)(c)(1)	**Hepatitis C direct-acting antivirals**	Deleted the language "…documentation is provided showing the recipient is unable to take ribavirin…"

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Appendix A (UU)(5)(c)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…Sovaldi, the requested duration is 16 weeks; and documentation is provided showing the recipient is unable to take ribavirin."
Appendix A (UU)(5)(c)(1)(c)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Section c.
Appendix A (UU)(5)(c)(2)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing the recipient is unable to take ribavirin, and must meet one of the following:"
Appendix A (UU)(5)(c)(2)(a)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or …"
Appendix A (UU)(5)(c)(2)(b)	**Hepatitis C direct-acting antivirals**	Added language, "Compensated cirrhosis (CTP class A), will be treated with Sovaldi, and the requested duration is 16 to 24 weeks, or …"
Appendix A (UU)(5)(c)(3) (a&b)	**Hepatitis C direct-acting antivirals**	New language is added for treatment-experienced recipients (failed Sovaldi + ribavirin dual therapy), documentation provided shows the recipient is unable to take peginterferon, must meet one: no cirrhosis, treated with Sovaldi and ribavirin, requested duration is 24 weeks; or no cirrhosis, will be treated with Sovaldi, requested duration is 24 weeks, documentation is provided showing the recipient unable to take ribavirin; or.
Appendix A (UU)(5)(c)(3) (c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads: "Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or…"
Appendix A (UU)(5)(c)(3)(d)	**Hepatitis C direct-acting antivirals**	Revised language now reads "Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin.
Appendix A (UU)(5)(d)(1) (b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads: "Compensated cirrhosis (CTP class A), will be treated with Sovaldi, and ribavirin, and the requested duration is 24 weeks; or"

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (UU)(5)(d)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…and documentation has been provided showing the recipient is unable to take ribavirin."
Appendix A (UU)(5)(d)(2)(b)	**Hepatitis C direct-acting antivirals**	Revised the language it now reads: "…ribavirin, the requested duration is 24 weeks, and documentation is provided showing the recipient is unable to take peginterferon."
Appendix A (UU)(5)(d)(2)(c)	**Hepatitis C direct-acting antivirals**	Deleted all the language in Section c.
Appendix A (UU)(6)(b)(1)(b)	**Hepatitis C direct-acting antivirals**	Deleted all the language in Section b.
Appendix A (UU)(6)(b)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(6)(b)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…polymorphism, documentation is provided showing the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(7)(b)(1)(a)	**Hepatitis C direct-acting antivirals**	The words "and ribavirin" have been deleted.
Appendix A (UU)(7)(b)(1)(b)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Section b.
Appendix A (UU)(7)(b)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "No cirrhosis, will be treated with Olysio, and the requested duration is 12 weeks, or"
Appendix A (UU)(7)(b)(1)(d-f)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Sections d, e and f.

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Appendix A (UU)(7)(b)(1)(g)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin, the requested duration is 24 weeks; and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(1)(h)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks, documentation is provided showing the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(1)(i)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(1)(j)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…polymorphism, documentation is provided showing the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(1)(k)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(1)(l)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks, documentation has been provided that the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen.
Appendix A (UU)(7)(b)(2)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks; and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(2)(d)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks, documentation is provided showing that the recipient is unable to take ribavirin, and documentation is provided

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		why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(2)(e)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks; the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(2)(f)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…polymorphism, documentation is provided showing that the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(2)(g)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(b)(2)(h)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks, documentation is provided showing the recipient is unable to take ribavirin, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(7)(b)(3)	**Hepatitis C direct-acting antivirals**	Deleted the language: "…has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir)…"
Appendix A (UU)(7)(c)(1)(b)	**Hepatitis C direct-acting antivirals**	Deleted the language "…documentation is provided showing the recipient is unable to take ribavirin…"
Appendix A (UU)(7)(c)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…duration is 16 weeks to 24 weeks…"
Appendix A (UU)(7)(c)(1)(d)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Section d.
Appendix A (UU)(7)(c)(1)(e)	**Hepatitis C direct-acting antivirals**	Deleted "24" replaced it with "16."
Appendix A (UU)(7)(c)(2)(a)	**Hepatitis C direct-acting antivirals**	Deleted "16" replaced it with "12."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (UU)(7)(c)(2)(b)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Section b.
Appendix A (UU)(7)(c)(2)(c)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…duration is 16 weeks to 24 weeks…"
Appendix A (UU)(7)(c)(2)(d)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…treated with Daklinza and ribavirin, the requested duration is 16 weeks to 24 weeks, and documentation is provided showing the recipient is unable to take rivabirin; or"
Appendix A (UU)(7)(c)(2)(e)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…peginterferon, the requested duration is 12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(7)(c)(3)(e)	**Hepatitis C direct-acting antivirals**	New language added: "Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks, documentation is provided showing the recipient is unable to take peginterferon and ribavirin."
Appendix A (UU)(7)(d)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(d)(1)(e)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…24 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(d)(1)(f)	**Hepatitis C direct-acting antivirals**	Deleted the language "…and documentation has been provided showing that the recipient is unable to receive peginterferon; or"
Appendix A (UU)(7)(d)(1)(g)	**Hepatitis C direct-acting antivirals**	Deleted language "…and showing the recipient is unable to receive peginterferon."
Appendix A (UU)(7)(d)(2)(d)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks, and documentation is provided showing the recipient is unable to take peginterferon."
Appendix A (UU)(7)(d)(2)(e)	**Hepatitis C direct-acting antivirals**	Deleted all the language in Section e.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (UU)(7)(d)(3)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…ribavirin, the requested duration is 24 weeks, and documentation is provided showing the recipient is unable to take peginterferon; or"
Appendix A (UU)(7)(d)(3)(d)	**Hepatitis C direct-acting antivirals**	Revised the language it now reads "…ribavirin, the requested duration is 24 weeks, and documentation is provided showing the recipient is unable to take peginterferon."
Appendix A (UU)(7)(e)(1)(a)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…peginterferon, the requested duration is 12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(e)(1)(b&d)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Sections b and d.
Appendix A (UU)(7)(e)(1)(c)	**Hepatitis C direct-acting antivirals**	Revised the language it now reads "Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen.
Appendix A (UU)(7)(e)(2)(a)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads "…peginterferon, the requested duration is 12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(e)(2)(b&c)	**Hepatitis C direct-acting antivirals**	Deleted all the language under Section b and c.
Appendix A (UU)(7)(e)(2)(d)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads, "…Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 12 weeks, documentation is provided why the recipient cannot take peginterferon, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(7)(f)(1)(a)	**Hepatitis C direct-acting antivirals**	New language added, it now reads: "…12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or"

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (UU)(7)(f)(1)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads, "Compensated cirrhosis (CTP class A), will be treated with ribavirin, and peginterferon, the requested duration is 12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(7)(f)(2)	**Hepatitis C direct-acting antivirals**	Added language, it now reads "…treatment-experienced, (failed peginterferon alfa + ribavirin dual therapy) and…"
Appendix A (UU)(7)(f)(2)(a)	**Hepatitis C direct-acting antivirals**	Revised language added, it now reads: "…peginterferon, the requested duration is 12 weeks, documentation is provided why the recipient cannot use a guideline-recommended regimen; or"
Appendix A (UU)(7)(f)(2)(b)	**Hepatitis C direct-acting antivirals**	Revised the language, it now reads, Compensated cirrhosis (CTP class A), will be treated with ribavirin, and peginterferon, the requested duration is 12 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen."
Appendix A (UU)(8)	**Hepatitis C direct-acting antivirals**	New criteria added for Zepatier® (elbasvir and grazoprevir).
Appendix A (UU)(8)(a)	**Hepatitis C direct-acting antivirals**	Added new language the requested dose is one (50/100) tablet daily.
Appendix A (UU)(8)(b)	**Hepatitis C direct-acting antivirals**	Added "Genotype 1a".
Appendix A (UU)(8)(b)(1)(a-d)	**Hepatitis C direct-acting antivirals**	New language added for treatment-naïve recipients: no cirrhosis, duration is 12 weeks and no NS5A RAVS for elbasvir detected, or; no cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs are detected, and documentation is provided why a guideline-recommended regimen can't be used, or; compensated cirrhosis, requested duration is 12 weeks, no NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected, documentation is provided why a guideline-recommended regimen cannot be used.
Appendix A (UU)(8)(b)(2)(a-d)	**Hepatitis C direct-acting antivirals**	New language added for treatment-experienced (failed peginterferon + ribavirin) dual therapy recipients: no cirrhosis, duration is 12 weeks and no NS5A RAVS for

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		elbasvir detected, or; no cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected, and documentation is provided why a guideline-recommended regimen can't be used, or; compensated cirrhosis, requested duration is 12 weeks, no NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected, documentation is provided why a guideline-recommended regimen can be used.
Appendix A (UU)(8)(b)(3)(a-d)	**Hepatitis C direct-acting antivirals**	New language added for treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) recipients: no cirrhosis, treated with ribavirin, duration is 12 weeks, no NS5A RAVs for elbasvir detected, or; no cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 12 weeks, no NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected.
Appendix A (UU)(8)(c)	**Hepatitis C direct-acting antivirals**	Added Genotype 1b.
Appendix A (UU)(8)(c)(1)(a&b)	**Hepatitis C direct-acting antivirals**	New language added for treatment-naïve recipients: no cirrhosis, requested duration is 12 weeks, or; compensated cirrhosis, requested duration is 12 weeks.
Appendix A (UU)(8)(c)(2)(a&b)	**Hepatitis C direct-acting antivirals**	New language added for treatment-experienced (failed peginterferon + ribavirin dual therapy) recipients: no cirrhosis, requested duration is 12 weeks, or; compensated cirrhosis, requested duration is 12 weeks.
Appendix A (UU)(8)(c)(3)(a&d)	**Hepatitis C direct-acting antivirals**	New language added for treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) recipients: no cirrhosis, treated with ribavirin, duration is 12 weeks, no NS5A RAVs for elbasvir detected, or; no cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 12 weeks, no NS5A RAVs detected, or; compensated cirrhosis, treated with ribavirin, duration is 16 weeks, NS5A RAVs detected.
Appendix A (UU)(8)(d)	**Hepatitis C direct-acting antivirals**	Genotype 4

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (UU)(8)(d)(1) (a-b)	**Hepatitis C direct-acting antivirals**	New language added for treatment-naïve recipients: no cirrhosis, requested duration is 12 weeks, or; compensated cirrhosis, requested duration is 12 weeks.
Appendix A (UU)(8)(d)(2) (a-c)	**Hepatitis C direct-acting antivirals**	New language added for treatment-experienced (failed peginterferon + ribavirin dual therapy) recipients: no cirrhosis, duration is 12 weeks, documentation provided shows the recipient experienced virologic response to peginterferon + ribavirin dual therapy, or; no cirrhosis, treated with ribavirin, duration is 16 weeks, documentation provided shows the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy, or; compensated cirrhosis, duration is 12 weeks, documentation shows recipient experienced virologic relapse to peginterferon+ ribavirin dual therapy.
Appendix A (UU)(9)	**Hepatitis C direct-acting antivirals**	Added language, it now reads, "…ombitasvir), or combination therapy with sofosbuvir + simeprevir."
Appendix A (UU)(9)(a)	**Hepatitis C direct-acting antivirals**	Deleted language "Genotype 1."
Appendix A (UU)(9)(c)	**Hepatitis C direct-acting antivirals**	Added new language, "The requested regimen does not include agents in which RAVs have developed."
Appendix A (UU)(9)(d)	**Hepatitis C direct-acting antivirals**	Added new language, "The regimen includes ribavirin or documentation shows ribavirin is contraindicated."
Appendix A (UU)(9)(3&4)	**Hepatitis C direct-acting antivirals**	All the language as numbered as Sections 3 and 4, have been deleted.
Appendix A (WW)	**Irritable-Bowel Syndrome Agents**	Updated the Therapeutic Class to "Irritable-Bowel Syndrome Agents." Revised the last reviewed by DUR Board date to July 28, 2016. Added: "Viberzi was last reviewed April 28, 2016." Updated the disclaimer for prior authorizations and quantity limits for "Irritable-Bowel Syndrome Agents…"
Appendix A (WW)(1)(a)	**Irritable-Bowel Syndrome Agents**	Added "Coverage and Limitations."

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		New language added: "Approval will be given if the following criteria are met and documented:"
Appendix A (WW)(1)(a)(1&2)	**Irritable-Bowel Syndrome Agents**	New criteria: the recipient is 18 years or older; the agent is prescribed based on FDA approval guidelines;
Appendix A (WW)(1)(a)(2)(a)(1&2)	**Irritable-Bowel Syndrome Agents**	New criteria: for Irritable-Bowel Syndrome with Constipation: libiprostone, the recipient is female; the requested dose is appropriate for indication and age:
Appendix A (WW)(1)(a)(2)(a)(2)(a&b)	**Irritable-Bowel Syndrome Agents**	New criteria: linaclotide: 145 μg daily; lubiprostone 290 μg daily.
Appendix A (WW)(1)(a)(2)(b)	**Irritable-Bowel Syndrome Agents**	New criteria: for requests for Irritable-Bowel Syndrome with Diarrhea (IBS-D):
Appendix A (WW)(1)(a)(2)(b)(1&2)	**Irritable-Bowel Syndrome Agents**	New criteria: the medication is prescribed by or in consultation with a gastroenterologist and the dose is appropriate based on indication and age.
Appendix A (WW)(1)(a)(2)(b)(2)(a&b)	**Irritable-Bowel Syndrome Agents**	New criteria: Alosetron: 0.5 mg twice daily or 1 mg twice daily, Eluxadoline: 75 mg twice daily or 100 mg twice daily, or Rifaximin: 550 mg three times a day for 14 days.
Appendix A (WW)(1)(a-e)	**Irritable-Bowel Syndrome Agents**	Deleted all the language Section 1, Sections a - e.
Appendix A (WW)(2)(a)	**Irritable-Bowel Syndrome Agents**	Under Prior Authorization Guidelines, the language is revised, it now reads: "…will be given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year."
Appendix A (YY)	**GnRH Analogs**	Added "Therapeutic Class: GnRH Analogs."
		Added "Last Reviewed by the DUR Board: July 28, 2016."
		Added standard disclaimer related to prior authorization and quantity limits.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A (YY)(1)	**GnRH Analogs**	Added "Coverage and Limitations."
Appendix A (YY)(1)(a)	**GnRH Analogs**	Added language: "This prior authorization criteria only applies to recipients under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:"
Appendix A (YY)(1)(a)(1)	**GnRH Analogs**	New criteria: "The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and …"
Appendix A (YY)(1)(a)(1) (a-d)	**GnRH Analogs**	New criteria: the requested dose and frequency are based on FDA-approved guidelines; medication is being prescribed by or in consultation with a pediatric endocrinologist, onset of secondary sex characteristics is before age 8 for females or age 9 for males; the recipient is less than age 11 for females or age 12 for males.
Appendix A (YY)(1)(a)(2) (a-c)	**GnRH Analogs**	New criteria for endometriosis: the dose and frequency is based on FDA approved guidelines; recipient has had an inadequate response to an NSAID or hormonal contraceptives.
Appendix A (YY)(1)(a)(3) (a-c)	**GnRH Analogs**	New criteria for uterine leiomyomata (fibroids): the requested dose and frequency is based on FDA approved guidelines, the recipient is symptomatic, documentation shows anticipated surgery date or surgery is planned after fibroid shrinkage or rationale why surgery is not required.
Appendix A (YY)(1)(a)(4) (a)	**GnRH Analogs**	New criteria for prostate cancer: the requested dose and frequency is based on FDA-approved guidelines.
Appendix A (YY)(2)(a)(1-4)	**GnRH Analogs**	New language for Prior Authorization Guidelines: CPP: One year or until recipient reaches the age of 11 (female) or 12 (male); Endometriosis: one year; Uterine leiomyomata (fibroids): one1 months or until the time of documented surgery (maximum three months); Prostate cancer: one year.
Appendix A (YY)(2)(b)	**GnRH Analogs**	New criteria: Prior Authorization forms are available at: (web address).

1203 POLICY

The Division of Health Care Financing and Policy (DHCFP), Nevada Medicaid, reimburses pharmacies and practitioners for legend (prescription) and non-legend (over the counter) pharmaceuticals dispensed or administered to Medicaid recipients. All prescribers must have a license as a healthcare practitioner, such as a physician, podiatrist, osteopath, dentist, Advanced Practice Registered Nurse (APRN), physician's assistant, etc., keeping within the scope of their practice. The DHCFP requires that pharmaceuticals are written, dispensed and prescribed in accordance with the Nevada State Board of Pharmacy regulations and enforcement.

1203.1 COVERAGE AND LIMITATIONS

1. Covered drugs are subject to prior authorization and/or quantity limits and the following:

    a. Section 1927(d)(1)(B)(i) of the Social Security Act (SSA) allows Medicaid to restrict coverage for an outpatient drug if the prescribed drug is not for a medically accepted indication. Section 1927(k)(6) defines a medically accepted indication as any use for a covered outpatient drug which is approved under the Federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia:

        1. American Hospital Formulary Service Drug Information;

        2. United States Pharmacopeia;

        3. DRUGDEX Information System; or

        4. Peer-reviewed medical literature.

    b. Pharmaceuticals must be manufactured by companies participating in the Federal Medicaid Drug Rebate Program.

    c. Medicaid is mandated by Federal statute to require all written (non-electronic) prescriptions for all outpatient drugs for Medicaid recipients to be on tamper-resistant prescription pads. This requirement does not apply to e-prescriptions transmitted to the pharmacy, prescriptions faxed to the pharmacy or prescriptions communicated to the pharmacy by telephone by a prescriber. Refer to Medicaid Services Manual (MSM) Addendum for more information on tamper-resistant prescription pads.

    d. The Preferred Drug List (PDL) is a list of preferred outpatient drugs established by the Pharmacy and Therapeutics (P&T) Committee. Reference Medicaid Operations Manual (MOM) Chapter 200 for the P&T bylaws. Pharmaceuticals not on the preferred drug list, but within drug classes reviewed by the P&T Committee, require prior authorization, unless exempt under Nevada Revised Statute (NRS) or

federal law or excluded through recommendations of the P&T Committee or excluded by the DHCFP.

1. New pharmaceutical products not within reviewed PDL drug classes and not excluded under the state plan or by NRS are covered without a Standard Preferred Drug List Exception prior authorization until or if the P&T Committee adds the drug class to the PDL and reviews the product or evidence.

2. New FDA approved drugs, or existing pharmaceutical products within reviewed PDL drug classes, for which there is new clinical evidence supporting its inclusion on the list of preferred prescription drugs and are not excluded under state plan or by NRS, are covered with an approved Standard Preferred Drug List Exception prior authorization until the P&T Committee can review the new evidence or drug.

3. Pharmaceuticals may require prior authorization due to step therapy protocols regardless of inclusion in the PDL.

4. If the P&T Committee determines that there are no significant differences between drugs within specific classes based on clinical efficacy and safety, the DHCFP or its Quality Improvement Organization (QIO)-like vendor may consider cost in determining which drugs are selected for inclusion on the PDL.

5. Due to the 76th Special Session and in accordance with Senate Bill (SB) 4, every therapeutic prescription drug that is classified as an anticonvulsant medication or antidiabetic medication that was covered by the Medicaid program on June 30, 2010 must be included on the PDL as a preferred drug. If a therapeutic prescription drug that is included on the list of preferred prescription drugs is prescribed for a clinical indication other than the indication for which it was approved as of June 30, 2010, the Committee shall review the new clinical indication for that drug in accordance with Section 1203 of this chapter.

6. Due to the 76th Special Session and in accordance with SB 4, the P&T Committee must prefer atypical and typical antipsychotic medications that are prescribed for the treatment of a mental illness, anticonvulsant medications and antidiabetic medications for a patient who is receiving services pursuant to Medicaid if the patient:

   a. was prescribed the prescription drug on or before June 30, 2010, and takes the prescription drug continuously, as prescribed, on and after that date; and

b. maintains continuous eligibility for Medicaid.

Reference Appendix A for coverage and limitations of medications with special criteria.

2. Standard Preferred Drug List Exception Criteria

Drugs that have a "non-preferred" status are a covered benefit for recipients if they meet the coverage criteria.

a. Coverage and Limitations

1. Allergy to all preferred medications within the same class;

2. Contraindication to or drug-to-drug interaction with all preferred medications within the same class;

3. History of unacceptable/toxic side effects to all preferred medications within the same class;

4. Therapeutic failure of two preferred medications within the same class;

5. If there are not two preferred medications within the same class therapeutic failure only needs to occur on the one preferred medication;

6. An indication which is unique to a non-preferred agent and is supported by peer-reviewed literature or a Food and Drug Administration (FDA)-approved indication;

7. Psychotropic, Antidepressant Medication – Continuity of Care

Recipients discharged from an institution on non-preferred psychotropic and/or non-preferred anti-depressant medication(s), their drugs will continue to be covered by Medicaid for up to six months to allow the recipient time to establish outpatient mental health services;

8. For atypical or typical antipsychotic, anticonvulsant and antidiabetic medications the recipient demonstrated therapeutic failure on one preferred agent.

b. Prior Authorization forms are available at:
http://www.medicaid.nv.gov/providers/rx/rxforms/aspx

3. Excluded

The ~~Nevada Medicaid Drug Rebate~~ DHCFP~~program~~ will not reimburse for the following pharmaceuticals:

a. Agents used for weight loss.

b. Agents used to promote fertility.

c. Agents used for cosmetic purposes or hair growth.

d. Yohimbine.

e. Drug Efficacy Study and Implementation (DESI) list "Less than Effective Drugs": In accordance with current policy, federal financial participation is not allowed for any drug on the Federal Upper Limit (FUL) listing for which the FDA has issued a notice of an opportunity for a hearing as a result of the DESI program which has been found to be a less than effective or is Identical, Related or Similar to the DESI drug. The DESI drug is identified by the FDA or reported by the drug manufacturer for purposes of the Medicaid Drug Rebate Program. This listing is available on the Centers for Medicare and Medicaid Services (CMS) website at: http://www.cms.gov/MedicaidDrugRebateProgram/12_LTEIRSDrugs.asp

This includes pharmaceuticals designated "ineffective" or "less than effective" (including identical, related or similar drugs) by the FDA as to substance or diagnosis for which prescribed.

f. Pharmaceuticals considered "experimental" as to substance or diagnosis for which prescribed. Pharmaceuticals manufactured by companies not participating in the federal Medicaid Drug Rebate Program unless rated "1-A" by the FDA.

g. Agents used for impotence/erectile dysfunction.

4. Refills

A refill is a prescription subject to the limitations below:

a. Authorized refills are valid only from the pharmaceutical provider dispensing the original prescription, pursuant to Nevada Administrative Code (NAC) Chapter 639.

b. Refill intervals must be consistent with the dosage schedule indicated on the original prescription. If a prescription is for a 34-day supply, a consistent refill would be filled in 30 days; an inconsistent refill date would be filled in 20 days

1. Antianginals*;
2. Antiarrhythmics*;
3. Anticonvulsants;
4. Antidiabetics*;
5. Antihypertensives*;
6. Cardiac Glycosides*;
7. Diuretics*;
8. Thyroid preparations;
9. Estrogens*;
10. Progesterone*; and
11. Oral/Topical Contraceptives*.

a. Drug classes identified with (*) are required to be dispensed in a 3-month (up to 100 day) supply, except for initial fills which can be dispensed in quantities of less than three months (100 days).

b. This requirement does not include skilled nursing facility pharmacies.

7. Emergency supply of medication

a. In an emergency situation, dispensing of up to a 96-hour supply of covered outpatient drugs that require prior authorization will be allowed.

b. Nevada Medicaid requires prior payment authorization for medications identified as requiring prior authorization.

c. The physician must indicate the diagnosis on the prescription (preferably with an International Classification of Disease (ICD) code) to support the use of the emergency policy.

d. As a follow-up to the dispensing of the emergency supply of medication, the provider must contact the QIO-like vendor, to obtain a verbal verification number.

e. An approved PA (if required) will be necessary to get additional medication.

be reimbursed. An administration fee is paid instead.

10. Pharmacist Submitted Prior Authorizations

    a. The DHCFP will allow pharmacists to submit a PA if:

        1. The requesting pharmacist has access to the recipient's medical records.

11. Dispensing Practitioners:

    a. Must have a current Certificate of Registration through the Nevada State Board of Pharmacy. Refer to NRS 639.070 and NAC 639.390, and

    b. Must be enrolled with Nevada Medicaid provider enrollment as a Provider Type 28, and

    c. Must have a separate NPI that must exclusively be utilized for billing of pharmacy services, and

    d. Dispensing practitioners' offices must be located in the State of Nevada, and

    e. All prior authorization criteria and quantity limitations apply to dispensing practitioner claims, and

    f. Only provider type 28 can be reimbursed for a dispensing fee, and

    g. All claims must be submitted in the NCPDP format through Medicaid's Point of Sale system, and

    h. All dispensing practitioners must be compliant with all applicable Board of Pharmacy statutes and regulations.

1203.1A PROVIDER RESPONSIBILITY

1. The pharmaceutical provider will maintain records for all prescriptions dispensed to eligible recipients as may be required.

    a. The provider will allow, upon request of proper representative, access to all records that pertain to Medicaid recipients for fiscal review, audit or utilization review.

    b. All fiscal records are to be maintained for a period of six years or as specified in federal regulation.

2. Utilization Control

a. Prospective (Concurrent) Drug Utilization Review (Pro-DUR)

Pro-DUR functions will be carried out via the ~~Point of Sale (~~POS~~)~~ Systems.

1. Pro-DUR edits apply to POS claims~~. and paper Uniform Claim Form (UCF) claims.~~

2. Long Term Care (LTC) claims are subject to all Pro-DUR edits that apply to retail.

3. Providers may submit override codes using the National Council for Prescription Drug Programs (NCPDP) standard interactive DUR codes. Override codes may be submitted on the initial claim. A denied claim does not have to be on file.

4. No long term override codes~~prior authorizations~~ are issued, codes must be entered each time errors occur. Reference the Nevada Medicaid and NCU Pharmacy Manual (Pharmacy Manual) for more information on the current Pro-DUR edits and override procedures.

5. All drugs are subject to quantity limitations. Refer to the Nevada Medicaid and NCU Pharmacy Manual for established quantity limits.

b. Retro Drug Utilization Review (DUR)

Both recipient and provider profiles (i.e. claim payments) are reviewed to identify patterns of excess. Verification of receipt of services is ongoing on a sample basis. Providers may be audited on site.

c. Drug Utilization Review (DUR)

Nevada Medicaid policy and federal law allows the state appointed DUR Board to conduct review of the information compiled about individual clients and providers and allows the DUR Board to educate Medicaid providers about the changes in drug therapeutics. Educational programs may include information such as drug interactions between medications that physicians have prescribed for the clients and medications they are prescribing that are unnecessarily expensive. In this case, educational efforts will be directed to help providers improve their efficiency in the allocation of the finite resources available for Medicaid clients.

d. Eligibility

Please refer to MSM Chapter 100 for information on Medicaid eligibility, eligibility verification and the Eligibility Verification System (EVS).

e. Lock-in Program: When a recipient has shown patterns of abuse/misuse of Nevada Medicaid benefits, or the DHCFP has determined that the recipient requires close medical management, the recipient may be "locked-in" to a specific pharmacy and/or provider. This means that Medicaid will only pay for controlled substance prescriptions/medical services at a single pharmacy/provider.

1. Criteria that is evaluated by the DHCFP when determining if a recipient should be locked in to a specific pharmacy begins with the number of controlled substance prescriptions filled in 60 days.

   If the recipient has filled ten or more controlled substance prescriptions in the past 60-day period (includes controlled substance pharmaceuticals given in the emergency room) then the clinical review continues with the following criteria:

   a. The recipient has utilized more than one pharmacy in the past 60-day period;

   b. The recipient has utilized more than three physicians in the past 60-day period;

   c. The recipient has utilized the emergency room(s) for receiving controlled substances;

   d. The recipient has been diagnosed with a drug dependency related condition;

   e. The dispensed quantity per prescription of controlled substances appears excessive by the clinical review team; or ~~T~~the recipient has other noted drug seeking behaviors(s).

2. The POS system will not allow another pharmacy to bill for controlled substance prescriptions, and a message will be given at the time of service to notify the pharmacy that the recipient is locked-in. Any non-controlled substance prescriptions can be filled at any pharmacy.

3. Recipients who are locked-in to one pharmacy can change their locked-in pharmacy at any time by contacting their Medicaid District Office.

and then stamped on the prescription.

d. A prior authorization is required to override genetic substitution.

e. Certification is not required if a generic is not manufactured.

f. A fax copy/verbal order may be taken by the pharmacist from the physician but the pharmacy must obtain an original printed copy and keep on file.

1203.1B SERVICE DELIVERY MODEL

For the rate and reimbursement methodology see MSM Chapter 700, Rates. For POS claims refer to the Pharmacy Manual, and for Medicaid Management Information System (MMIS) claims refer to the Nevada Medicaid and NCU Billing Manual (Billing Manual).

1. Institutional settings

a. Medical/Surgical, Specialty, ~~and~~ Psychiatric Hospitals and free-standing inpatient hospice facilities – All pharmacy services are included in the daily per diem rate for inpatient services, which are billed through MMIS.

b. Long Term Care (LTC)

1. Nursing Facilities (NF) – Legend (prescription) pharmaceutical services are excluded from the daily per diem facility rate. This includes compound prescriptions and Total Parental Nutrition (TPN) solution and additives. Legend pharmaceuticals are billed separately directly by a licensed pharmacy through POS.

Non-legend (over the counter) pharmaceuticals are not separately reimbursable by the DHCFP.

2. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) – Legend and non-legend pharmaceuticals are excluded from the facility rate. Pharmaceuticals are billed directly by a licensed pharmacy through POS.

3. Hospice services in NFs, all drugs related to the documented terminal illness and palliative, symptom relief are to be covered by the hospice and will not be reimbursed by the DHCFP. Refer to MSM Chapter 3200, Hospice, for more information.

2. Outpatient Pharmaceuticals

a. Covered outpatient drugs (COD(s)) ~~that~~ are ~~billed~~reimbursed separately from

medical services, in the following settings, in accordance with Section 1927 of the Social Security Act~~dministration~~ (SSA).

1. Retail pharmacies (billed through POS).

2. Home Infusion Therapy (HIT)/Free Standing Infusion Clinics, (billed through POS). ~~Refer to the Intravenous (IV) Therapy Provider Type 37 Section of this chapter.~~

   a. Disposable supplies are billed separately with a 33 Provider Type number (billed through MMIS).

   b. Refer to the Nevada Medicaid and Check Up Pharmacy Billing Manual.

3. COD(s) ~~Physician~~ administered ~~drugs~~in an outpatient setting, such as a physician's office (NVPAD).~~all pharmacy charges are billed separately.~~

   a. ~~The~~ COD(s)~~administered drug is~~ are ~~to be~~ billed utilizing the appropriate National Drug Code (NDC) and NDC quantity (billed through MMIS).

   b. The administration of the drug is billed using the appropriate Current Procedural Terminology (CPT) code (billed through MMIS).

4. Hospital based outpatient clinics.~~, all pharmacy charges are billed separately.~~

   a. COD(s)~~The administered drug~~ are ~~is to be~~ billed utilizing the appropriate NDC and NDC quantity (billed through MMIS).

   b. The administration of the drug is billed using the appropriate CPT code, (billed through MMIS).

5. End Stage Renal Disease (ESRD) Facilities.~~,~~

   a. A~~a~~ny COD(s)~~administered drugs~~ not included in the Prospective Payment System (PPS) Rate are ~~to be~~ billed using the appropriate NDC and NDC quantity.

   b. The administration of the drug is billed using the appropriate CPT code, (billed through MMIS).

c. COD(s)~~Drugs~~ included in the PPS Rate as documented in the CMS Manual System, Publication # 100-04, Medicare Claims Processing, Transmittal 2134 will deny if billed separately.

6. Emergency Rooms.~~,~~

a. COD(s) are billed utilizing the appropriate NDC and NDC quantity ~~all pharmacy services are included in the Emergency Room charges. "Take home" medications are also included in the facility rate and may not be billed separately,~~ (billed through MMIS).

b. COD~~sovered outpatient drugs that~~ are not reimbursed separately, in the following settings, in accordance with 1927(k)(2) of the SSA.

1. Ambulatory Surgical Centers (ASC)./~~Hospital Based Ambulatory Infusion Centers,~~ COD(s)~~all pharmacy services~~ are included in the facility rate. COD(s)~~Pharmacy charges~~ may not be billed separately~~, (billed through MMIS)~~.

2. Outpatient facilities/clinics/FQHCs that are paid per encounter, cannot be reimbursed separately for CODs when drugs are included in their encounter rate.

3. Outpatient hospice reimbursement for CODs related to the documented terminal illness and palliative, symptom relief, are to be covered by the hospice and will not be reimbursed by the DHCFP. Refer to MSM Chapter 3200, Hospice, for more information.

~~2.1. Emergency Rooms, all pharmacy services are included in the Emergency Room charges. "Take home" medications are also included in the facility rate and may not be billed separately, (billed through MMIS).~~

3. Disposable Medical Supplies

Please refer to MSM Chapter 1300, Durable Medical Equipment (DME), for instructions on billing and any applicable limitations for these items.

4. Unit Dose (Repackage and Re-Stock) Repackage

Nevada Medicaid provides reimbursement incentives for LTC providers who repackage non-unit dose pharmaceuticals; An additional $0.43 per claim is given on pharmaceuticals that are repackaged for unit dose dispensing. Pharmaceuticals that First Data Bank classifies as unit dose products are not covered for this policy.

This incentive is available only to pharmacies supplying long-term care inpatients. The pharmacy provider must apply to the QIO-like Vendor Pharmacy Department to enroll in

this incentive program.

In accordance with the CMS, State Medicaid Director Letter (SMDL) 06-005, repackaging of pharmaceuticals must be in compliance with the Nevada State Board of Pharmacy. In addition, NFs must properly credit the Medicaid program for the return of unused prescription medicines upon discontinuance of the prescription or transfer, discharge or death of a Medicaid beneficiary. This is to assure there is no double billing of the medication.

~~5. Coordination of Benefits (COB)~~

~~On-line COB (cost avoidance) is part of the Nevada Medicaid POS system.~~

~~a. If Nevada Medicaid is the recipient's secondary carrier, claims for COB will be accepted.~~

~~b. Nevada Medicaid is always the payer of last resort.~~

~~c. Other coverage will be identified by the presence of other carrier information on the recipient eligibility file.~~

~~d. If the recipient shows other coverage, the claim will be denied. The POS system will return a unique client identified carrier code identifying the other carrier, the recipient's policy number and the carrier name in the additional message filed. It is possible that a recipient may have more than one active other carrier; in that case, the returned code will be from the first carrier, subsequent codes will be returned until fully exhausted. Providers will be required to submit this code OTHER PAYER ID (#340-7C) field as part of the override process.~~

~~e. Even if "no other insurance" is indicated on the eligibility file, the claim will be processed as a TPL claim if the pharmacy submits.~~

~~f. If other insurance is indicated on the eligibility file, the claim will be processed as a TPL regardless of what TPL codes the pharmacy submits.~~

~~g. In all cases, the Nevada Medicaid "allowed amount" will be used when calculating payment. In some cases, this may result in a "0" payment, when the insurance carrier pays more than the Medicaid "allowable amount."~~

~~h. In order to facilitate the TPL/COB process, Nevada Medicaid will allow providers to override "days supply limits" and/or "Drug Requires PA" conditions by entering a value of "5" (exemption from prescription limits) in the PA/MC CODE field (NCPCP #416DG) if there are no prior authorization requirements on these drugs from the primary insurer.~~

6. Non-participating Health Maintenance Organization (HMO) Providers

a. Recipients, who have Medicaid and HMO coverage, including Medicare HMOs, must seek treatment and services through their preferred provider network or HMO. Nevada Medicaid is not liable to pay for HMO covered services if the recipient elects to seek treatment from a provider not authorized by the HMO. Unless the provider is an authorized provider of a recipient's health plan, the recipient should be referred to the plan for covered treatment, or the provider should contact the HMO for treatment authorization. Refer to MSM Chapter 3600, Managed Care Organizations (MCO), or MSM Chapter 100, Medicaid Program, for more information.

b. Exceptions to Medicaid liability policy are:

1. The service(s) is/are a non-covered benefit of the HMO plan;

2. The service is an emergency and a participating provider is more than 25 miles away;

3. The service is for family planning;

4. The recipient resides outside the service area of the HMO; or

5. The recipient's HMO coverage has been exhausted.

7. Pharmacy Billing Process

a. NCPDP Standard Billing Units

Nevada Medicaid reimburses for outpatient pharmaceuticals according to NCPDP "Billing Unit Standard Format" guidelines. The standard provides for the billing of pharmaceuticals in one of three billing units for all drug products. These units are "each," "milliliter (ml)," and "gram (g)." The following guidelines are to be used when billing Nevada Medicaid for pharmaceuticals:

Tablets, Capsules, Suppositories, Pre-filled Syringes: must be billed by "each" or by "mls." For example, if 30 tablets of Metformin are dispensed, the quantity will be 30.

Liquids, Liquid Orals, Suspensions, Solutions, Opthalmic/Otic Solutions: must be billed by milliliters (mls). For example, if 560ml of guiafenesin is dispensed, the quantity entered will be 560.

PLEASE NOTE:

Ounces must be converted to ml (1 ounce = 30ml).
Liters must be converted to ml (1L = 1000ml).

~~Ointments, Bulk Powders: must be billed by grams. For example, if a two ounce tube of oxiconazole nitrate is dispensed, the quantity entered will be 60.~~

~~PLEASE NOTE:~~
~~Ounces must be converted to grams (1 ounce = 30g, ½ ounce = 15g). Oral Contraceptives/Therapy packs: must be billed per "each" tablet dispensed, not the number of packages. For example, Ortho Tri-Cyclen is a 28-day dial pack, the quantity entered will be 28.~~

~~Transdermal Patches/Powder Packets: must be billed per "each" patch/packet dispensed, regardless of whether they are pre-packaged in a box or come in individual pouches/packets. For example, Catapress-TTS comes in a box of four patches. If two of these boxes are dispensed, the quantity entered will be eight.~~

~~Inhalers and Aerosols: must be billed as either grams or ml, as specified by the manufacturer on the labeling. For example a 90mcg(microgram)/inh Albuterol Inhaler has a total of 17gm in the canister. If one of these is dispensed, 17 will be quantity entered.~~

~~Topical Products: must be billed as either grams or ml, as specified by the manufacturer on the labeling.~~

~~PLEASE NOTE: Ounces must be converted to grams or ml.~~

~~1 ounce = 30ml~~
~~1 ounce = 30g~~

~~Reconstitutables (oral, otic, ophthalmic): must be billed per ml that are/will be in the bottle after reconstitution according to the manufacturer's instructions.~~

~~Liquid Injectables (vials, ampoules): must be billed by milliliters (ml). For example, if a 10ml vial of Novolin 70/30 is dispensed, the quantity entered will be 10.~~

~~Powdered Injectables (vials): must be billed by "each" vial given per dose. For example if the recipient receives Ampicillin 1g every six hours for one week, the quantity entered will be 1, as only one vial is used per dose (assuming a 1gm vial is used), and the # of doses entered will be 28 (4 per day x 7 days).~~

~~PLEASE NOTE: If the product is supplied with a diluent, the quantity entered is only the number of powdered vials dispensed, the diluent is not factored in.~~

~~Intravenous Solutions: must be billed in ml administered per dose. For example, if a recipient receives 250ml of Normal Saline four times per day, the quantity entered will be 250, as that is the quantity per dose.~~

~~Blood Derived Products: products may vary in potency from batch to batch. Anithemophilic products must be billed as the number of antihemophilic units dispensed (each). Prolastin must similarly be billed as the number of milligrams dispensed (each).~~

~~Kits: defined as products with a least two different or discreet items (excluding diluents, applicators and activation devices) in the same package, intended for dispensing as a unit. Kits carry only a single NDC. Kits are intended to be dispensed as a unit and should be billed as a unit of each kit dispensed (each).~~

~~For further information, refer to the NCPDP Billing Unit Standard Format Official Release.~~

~~b. Provider Numbers~~

~~The state National Association of Boards of Pharmacy (NABP) provider number is to be used and entered when billing online using the POS system or when using the UCF.~~

8. State Maximum Allowable Cost (SMAC)

a. SMAC is the upper reimbursement limit for multi-source outpatient pharmaceuticals established by the DHCFP or QIO-like vendor~~Fiscal Agent~~.

1. The DHCFP or QIO-like vendor~~Fiscal Agent~~ will perform ongoing market analysis to monitor pricing patterns and product availability.

2. The DHCFP or QIO-like vendor~~Fiscal Agent~~ will perform monthly updates of the drugs subject to the SMAC.

3. All drugs subject to the SMAC and updates will be posted on the following website: http://www.medicaid.nv.gov/providers/rx/MACinfo.aspx

b. Providers may appeal the current SMAC for a pharmaceutical product if a provider determines that a particular multi-source drug is not available at the current SMAC reimbursement.

1. The pharmacy must contact the QIO-like vendor~~Fiscal Agent~~ technical call center to initiate the appeal.

2. Information needed to make a decision will include the NDC number, manufacturer, drug name, strength and price paid. A faxed copy of the actual invoice for the drug may be requested.

3. Inquiries not resolved by the technical call center are forwarded to the QIO-

like vendor's~~Fiscal Agent's~~ SMAC Coordinator for investigation and resolution.

4. If it is determined the SMAC is negatively impacting access to care for recipients, the SMAC Coordinator has the authority to:
   a. adjust SMAC pricing for the particular claim being appealed; and

   b. make changes to the SMAC pricing file.

5. Appeals will be responded to within three working days of the referral to the SMAC Coordinator.

1203.1C PRIOR AUTHORIZATION (PA) PROCEDURES

~~Prior Authorization Requests: Physician's may request payment for exceptions to program limitations and medications requiring prior authorization by forwarding a prior authorization request to the QIO-like vendor.~~

1. Prior authorization requests may be done via phone, fax or via the internet. ~~Refer to the Pharmacy Manual for more information.~~A facsimile signature stamp is acceptable on faxed prior authorization requests.

2. PA requests must be submitted on the appropriate Prior Authorization Request form. Pharmacy PA forms can be found at the following web site: https://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. LTC drug claims, are subject to PA requirements.

4. The QIO-like vendor will process the PA request within 24 hours of receipt.

   a. The requesting practitioner will be advised of the PA status (approval, denial, pending further information) within 24 hours of the receipt.

   b. For PA requests in which the QIO-like vendor has pended the request for further information, the prior authorization will deny if the practitioner does not respond to a request for further information within three working days.

5. An approved PA will be entered in the POS system prior to the dispensing of the medication. There may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).

6. The Nevada Medicaid QIO-like vendor will send all Notice of Decision denial of service letters. Reference MSM Chapter 3100 for the information on hearings.

7. Refer to the Nevada Medicaid and Check Up Pharmacy Billing Manual for more information.

~~1. When requesting a prior authorization, providers must:~~

~~a. Provide all relevant diagnoses.~~

~~b. List all routine essential drugs being prescribed.~~

~~c. The requesting physician will be advised of the decision within 24 hours of receipt. A facsimile signature stamp is acceptable on faxed prior authorization requests.~~

~~d. Unless otherwise indicated by the QIO-like vendor, the prior authorization is for no more than one 34-day supply of prescription for each authorized drug per month.~~

~~2. Prior Authorization Protocols~~

~~a. Alternate media (e.g. paper/UCF claims) are subject to all prior authorization types. LTC claims, regardless of the media type, are subject to all prior authorization types. Note that the POS system does not require a "Prior Authorization Number" to be entered on a paper or electronic claim; the only requirement is that the prior authorization record is activated in the system prior to the claim submission. The approved prior authorization will be in the POS system and will be active for all pharmacies using the POS system, unless the recipient is "locked-in" to a particular pharmacy for abuse/misuse reasons.~~

~~b. A prior authorization will typically be required to be requested and entered prior to the dispensing of the medication, however there may be situations in which an authorization request is considered after the fact (e.g. retroactive eligibility).~~

~~c. For clinical prior authorizations in which a Clinical Call Center Prior Authorization Unit pharmacist or pharmacy technician requests information from the prescribing physician, the prior authorization will deny if the doctor does not respond to a request for information within three working days.~~

~~d. The Nevada Medicaid QIO-like vendor will send all denial of service letters.~~

~~e. For any prior authorization requests that are denied due to criteria not being met, the recipient (only) may appeal the decision. Reference MSM Chapter 3100 for the hearings process.~~

~~f. Standard protocols for "Emergency" or "72-96 Hour Fill" type of overrides will be used.~~

1203.2 INTRAVENOUS (IV) THERAPY ~~PROVIDER TYPE 37~~

~~The purpose of IV therapy is to sustain life, reduce or eliminate infections, replace or provide necessary chemicals to maintain electrolyte balance or provide blood product or hemotherapeutics. IV therapy and treatment should only be used when the Medicaid recipient cannot use oral medications.~~

For specific instructions related to billing via the POS system, refer to the Nevada Medicaid Check-Up Pharmacy Billing Manual.

a. Billing Guidelines

IV therapy is billed through the pharmacy POS system using the multi-ingredient functionality. ~~A 37 provider number is required (Home Infusion Therapy Provider). The paper Multi-ingredient UCF may also be used if an exception is granted by the Division.~~ Drug coverage edits and prior-authorization edits will be processed~~performed~~ at the individual ingredient level.

~~The billing units used should be the NCPDP standards of "each," milliliters (ml) or grams (g). Please refer to section 1203.1(D)(8) of this Chapter for complete explanation of these standards.~~

~~For specific instructions related to billing via the POS system, refer to the Nevada Medicaid QIO-like pharmacy vendor.~~

~~b. Dispensing Fees~~

~~A daily dispensing fee of $22.40 will be applied to IV therapy claims for outpatient antibiotic therapy. For recipients in LTC, a daily dispensing fee of $16.80 will be applied to the claim. This will be multiplied by the number of days the therapy was provided.~~

~~c. Supplies~~

~~Supplies for IV therapy, Enteral Nutrition and TPN are billed through the DME program (under Provider Type 33). Please refer to MSM Chapter 1300, DME, Disposable Supplies and Supplements, for instructions on billing and any applicable limitations on these items.~~

b. ~~d.~~ Long Term Care (LTC)

1. For recipients in LTC, a daily dispensing fee of $10.17 will be applied to IV therapy claims. This dispensing fee will be multiplied by the number of days the therapy was provided

~~1.~~a. Non-Billable Items

IV hydration therapy of standard fluids without additives (e.g., antibiotics, potassium and heparin) and~~as well as~~ supplies ~~only~~ associated with IV therapy,

~~E~~enteral ~~N~~nutrition and TPN administration are included in Nevada Medicaid's LTC/NF rate and may not be billed as a separate charge.

~~2.~~b. Billable Items

IV Drugs/TPN for recipients in LTC facilities may be billed as a separate charge. ~~Please r~~Refer to MSM Chapter 500 (Nursing Facilities) for further information~~. on items which may be billed separately to Nevada Medicaid.~~

P. Monoclonal Antibody Agents~~Xolair® (Omalizumab)~~

Therapeutic Class: Respiratory Monoclonal Antibody Agents
Last Reviewed by the DUR Board: July 28, 2016
Xolair previously reviewd: July 24, 2014 and April 23, 2015

Xolair® (Omalizumab) is subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Xolair® (Omalizumab)

1. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies.

2. All of thefollowing criteria must be met and documented for a diagnosis of moderate to severe persistent asthma:~~Approval will be given if the following criteria are met and documented: Recipients must meet at least one condition (a. or b.) listed below:~~

~~a. The recipient must have a diagnosis of moderate to severe persistent asthma; and~~

~~The recipient must meet all of the following criteria:~~

a. ~~1.~~ The recipient must be age 12 years of age or older; and

b. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen; and

c. The prescriber must be either a pulmonologist or allergist/immunologist; and

d. ~~2.~~ The recipient must have ~~tried and failed, or have a contraindication~~ had an inadequate response, adverse reaction or contraindication to inhaled, oral corticosteroids; and

e. ~~3.~~ The recipient must have had an inadequate response, adverse reaction or ~~tried and failed, or have a~~ contraindication to an oral second generation antihistamine; and

f. ~~4.~~ The recipient must have had an inadequate response, adverse reaction or~~tried and failed, or have a~~ contraindication to a leukotriene receptor antagonist; and

~~5. The prescriber must be either a pulmonologist or allergist/immunologist; and~~

~~6. The recipient must have a history of a positive skin test or Radioallergosorbent (RAST) test to a perennial aeroallergen;~~

g. ~~7.~~ The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level between 30 IU/mL and 700 IU/mL; and

h. ~~8.~~ The recipient's current weight must be recorded; and

i. ~~9.~~ The requested dose is appropriate for the recipient's pre-treatment serum IgE and body weight (see Table 1).

~~1.~~3. All the following criteria must be met and documented for diagnosis of ~~The recipient has a diagnosis of~~ chronic idiopathic urticaria (CIU~~L~~), and

~~The recipient must meet all of the following criteria:~~

a. The recipient is age 12 years of age or older;

~~a.~~b. The recipient must have had an inadequate response, adverse reaction or ~~tried and failed, or have a~~ contraindication to two different oral second generation antihistamines; and

~~b.~~c. The recipient must have had an inadequate response, adverse reaction or ~~tried and failed, or have a~~ contraindication to an oral second generation antihistamine in combination with a leukotriene receptor antagonist; and

d. The prescriber must be either an allergist/immunologist, dermatologist or a rheumatologist or there is documentation in the recipient's medical record that a consultation was done by an allergist/immunologist, dermatologist or a rheumatologist regarding the diagnosis and treatment recommendations; and

~~c.~~e. The requested dose is:

1. Initial therapy: 150 mg every four weeks or 300 mg every four weeks and clinical rational for starting therapy at 300 mg every four weeks has been provided.

2. Continuation of therapy: 150 mg or 300 mg every four weeks.

b. Nucala® (mepolizumab), Cinqair® (reslizumab)

1. All the following criteria must be met and documented:

a. The recipient will not use the requested antiasthmatic monoclonal antibody in combination with other antiasthmatic monoclonal antibodies; and

b. The recipient must have a diagnosis of severe eosinophilic-phenotype asthma; and

c. The recipient must be an appropriate age:

1. Mepolizumab: 12 years of age or older

2. Reslizumab: 18 years of age or older

d. And, the prescriber must be either a pulmonologist or allergist/ immunologist; and

e. The recipient must be uncontrolled on current therapy including high dose corticosteroid and/or on a secondary asthma inhaler; and

f. There is documentation of the recipient's vaccination status; and

g. The requested dose is appropriate:

1. Mepolizumab: 100 mg subcutaneously every four weeks,

2. Reslizumab: 3 mg/kg via intravenous infusion of 20 to 50 minutes every four weeks.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for 12 months.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

Table 1: Dosing for Xolair® (omalizumab)*

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥30-100	150 mg	150 mg	150 mg	300 mg
>100-200	300 mg	300 mg	300 mg	225 mg
>200-300	300 mg	225 mg	225 mg	300 mg
>300-400	225 mg	225 mg	300 mg	
>400-500	300 mg	300 mg	375 mg	

>500-600	300 mg	375 mg
>600-700	375 mg	**DO NOT DOSE**
Every 2 Weeks Dosing		
Every 4 Weeks Dosing		

Z. Opioids~~Cymbalta® (duloxetine)~~

Therapeutic Class: Opioids~~Sertonin-Norepinephrine Reuptake Inhibitor (SNRI)~~
Last Reviewed by the DUR Board: October 27, 2016~~July 25, 2013~~

Opioids~~Cymbalta® is~~ are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Opioids will be covered without Prior Authorization (PA):

1. For initial prescriptions of seven days or less, and

2. For a total of thirteen seven-day prescriptions in any rolling 12 month period, and

3. For prescriptions of 60 mg morphine equivalents or less per day.

b. Recipients currently on chronic opioid medications will not be subject to the seven-day requirement for an opioid(s) they have been receiving in the past 45 days.

c. Prior Authorization Criteria: To exceed the number of seven-day prescriptions, or to exceed the seven-day limit, or to exceed the 60 mg morphine equivalents or less per day:

1. All of the following criteria must be met and documented:

a. The recipient has chronic pain or requires an extended opioid therapy and is under the supervision of a licensed prescriber, and

b. Pain cannot be controlled through the use of non-opioid therapy (acetaminophen, NSAIDs, antidepressants, anti-seizure medications, physical therapy, etc.) and

c. The lowest effective dose is being requested, and

d. A pain contract is on file.

d. Exceptions to this policy:

1. Recipients with cancer/malignancy related pain, or

2. Recipients who are post-surgery with an anticipated prolonged recovery (greater than three months), or

3. Recipients receiving palliative care, or

4. Recipients residing in a long-term care facility, or

5. Recipients receiving treatment for HIV/AIDS, or

6. Prescriptions written by or in consultation with a pain specialist.

2. Prior Authorization Guidelines

a. Prior Authorization approval will be for one year.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

3. CDC Guidance:

a. http://www.cdc.gov/drugoverdose/prescribing/guideline.html.

~~Approval will be given if the following criteria are met and documented. Recipients must meet at least one diagnosis listed below:~~

~~a. Diabetic Peripheral Neuropathy (DPN):~~

~~1. If an ICD code for Diabetes with Neurological Manifestations is documented on the prescription and transmitted on the claim; or~~

~~2. Completion of a prior authorization documenting a diagnosis of Diabetes with Neurological Manifestations.~~

~~b. Fibromyalgia:~~

~~1. If an ICD code for Fibromyalgia, Myalgia and Myositis unspecified is documented on the prescription and transmitted on the claim; or~~

~~2. Completion of a prior authorization documenting a diagnosis of Fibromyalgia and/or Myalgia and Myositis, unspecified.~~

~~c. Chronic Musculoskeletal Pain:~~

~~The recipient must meet one of the following:~~

~~1. The recipient has experienced an inadequate response or adverse event to at least two oral or topical non-steroidal anti-inflammatory drug (NSAIDS); or~~

2. The recipient has an allergy or contraindication to two NSAIDS.

d. Generalized Anxiety Disorder:

The recipient must meet the following:

1. The recipient has experienced an inadequate response or adverse event to at least two antidepressants from any of the following classes: selective serotonin reuptake inhibitors, tricyclic antidepressants, serotonin and norepinephrine reuptake inhibitors or buspirone.

e. Major Depressive Disorder:

The recipient must meet the following:

1. The recipient has experienced an inadequate response, and/or adverse event and/or an allergy and/or contraindication to at least two antidepressants.

2.1.Prior Authorization Guidelines

a. Prior Authorization approval will be for one year.

b.c. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

UU. Hepatitis C direct-acting antivirals

Therapeutic Class: Hepatitis C direct acting antivirals
Last Reviewed by the DUR Board: ~~January 28, 2016~~July 28, 2016
Previously reviewed by the DUR Board: January 28, 2016

Hepatitis C direct-acting antivirals are subject to prior authorization and quantity limitations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations:

   a. Approval will be given if the following criteria are met and documented.

   b. Recipients must meet all of the following criteria:

      1. The recipient has a diagnosis of chronic Hepatitis C Virus (HCV) infection; and

      2. The recipient is 18 years of age or older; and

      3. All of the following must be included with the PA request:

         a. Medical records and results of laboratory and diagnostic tests which support all of the following:

            1. The HCV genotype (and subtype, if applicable); and

            2. The baseline HCV RNA viral load and date drawn; and

            3. The hepatic fibrosis stage, including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4). (Results of diagnostic tests or imaging studies that are inconclusive may require additional testing); and

         b. A complete treatment regimen; and

         c. The duration of treatment; and

         d. Any previous treatment experience and length of treatment, if any, including outcome (e.g. discontinued due to side effects, relapsed, non-responder, null-responder); and

      4. The prescriber must certify that the treatment will be discontinued if the viral load is detectable at week four of treatment and has increased by

greater than 10-fold (>1 $\log_{10}$ IU/mL) on repeat testing at week six (or thereafter); and

5. Requests for recipients with decompensated cirrhosis (Child Turcotte Pugh (CTP) class B or C) and requests for recipients who have chronic hepatitis C infection status-post liver transplant will be evaluated on a case by case basis.

2. Harvoni® (ledipasvir/sofosbuvir) Initial Requests

a. The requested dose is one 90 mg/400 mg tablet once daily.

b. Genotype 1:

1. The recipient is treatment naïve and must meet one of the following:

a. No cirrhosis, pre-treatment HCV RNA < six million, and the requested duration is eight weeks; or

b. No cirrhosis, pre-treatment HCV RNA ≥ six million, and the requested duration is 12 weeks; or

c. Compensated Cirrhosis (CPT class A), requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) will be treated with ribavirin, and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin and the requested duration is 24 weeks.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + an NS3 protease inhibitor), ~~has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir)~~ and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), documentation is provided that the recipient is unable to take ribavirin, and the requested duration is 24 weeks.

~~4. The recipient is treatment-experienced (failed Olysio + Sovaldi), has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir), and must meet one of the following:~~

~~a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or~~

~~b. Cirrhosis (CTP class A, B, or C) will be treated with ribavirin and the requested duration is 24 weeks.~~

~~1.~~4. The recipient is treatment-experienced (failed Sovaldi + ribavirin ± peginterferon) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated ~~C~~cirrhosis (CTP class A~~, B, or C~~), will be treated with ribavirin and the requested duration is 24 weeks.

c. Genotype 4~~, 5, 6~~:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks, or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin), and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks, or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, and the requested duration is 12 weeks, or

c. Compensated cirrhosis (CTP class A), documentation is provided the recipient is unable to take ribavirin, and the requested duration is 24 weeks.

d. Genotype 5 and 6:

1. The recipient is treatment-naïve and the requested duration is 12 weeks; or

2. The recipient is treatment-experienced (failed peginterferon + ribavirin ~~± an NS3 protease inhibitor~~) and the requested duration is 12 weeks.

3. Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir) (Initial Requests)

a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg) and one dasabuvir 250 mg tablet twice daily.

b. Genotype 1a:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin, and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is ~~12~~ 24 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, recipient will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the recipient requested duration is 24 weeks, and documentation is provided why the recipient cannot use a guideline-recommended regimine.~~was a partial responder to peginterferon and ribavirin dual therapy and the requested duration is 12 weeks; or~~

~~c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the recipient was a relapser after peginterferon and ribavirin dual therapy and the requested duration is 24 weeks.~~

c. Genotype 1b:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

4. Technivie® (ombitasvir/paritaprevir/ritonavir) (Initial Requests)

a. The requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily (25/150/100 mg); and

~~b. The recipient does not have cirrhosis.~~

~~c.~~b. Genotype 4:

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, ~~T~~the recipient ~~is treatment-naïve,~~ will be treated with ribavirin and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.~~The recipient is treatment-naïve, provided documentation shows the recipient is unable to take ribavirin and the requested duration is 12 weeks; or~~

~~c.~~2. The recipient is treatment-experienced (failed peginterferon and ribavirin dual therapy) and must meet one of the following:

~~d.~~a. No cirrhosis, the recipient will be treated with ribavirin and the requested duration is 12 weeks.

b. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 12 weeks.

5. Daklinza® (daclatasvir) (Initial Requests)

a. The requested dose is one of the following:

1. 60 mg (one tablet) daily; or

2. 30 mg (one tablet) and the recipient is receiving a strong CYP3A inhibitor; or

3. 90 mg (one ~~30 mg tablet and one 60 mg~~ tablet) daily and the recipient is receiving a concomitant moderate CYP3A inducer~~. and the clinical rationale has been provided documenting medical necessity for continuing the moderate CYP3A inducer Daklinza therapy.~~

b. Genotype 1

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi ~~and ribavirin~~ and the requested duration is 12 weeks; or

~~b. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or~~

~~c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi ± ribavirin and the requested duration is 12 weeks; or~~

~~d.~~b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi + ribavirin~~, and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~e.~~c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks~~, and~~ documentation has been provided showing the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin~~, and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended reg; or

c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks~~, and~~ documentation is provided

showing that the recipient is unable to take ribavirin and documentation is provided shy the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) ~~has had no prior treatment with an NS5A polymerase inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir)~~ and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing that the recipient is unable to take ribavirin.

c. Genotype 2

1. The recipient is treatment-naïve ~~documentation is provided showing the recipient is unable to take ribavirin,~~ and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi~~, and~~ the requested duration is ~~12~~ 16 weeks and documentation is provided showing the recipient is unable to take ribavirin.~~; or~~

~~c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 24 weeks.~~

2. The recipient is treatment-experienced (failed peginterferon~~Sovaldi~~ + ribavirin dual therapy), documentation is~~has been~~ provided showing ~~that~~ the recipient is unable to take ribavirin~~receive peginterferon~~ and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi ~~and ribavirin~~ and the requested duration is ~~24~~ 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and the requested duration is 16 to 24 weeks, or

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy), documentation has been provided showing the recipient is unable to take peginterferon and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

b. No cirrhosis, will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take ribavirin; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks;~~.~~ or

d. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation is provided showing the recipient is unable to receive ribavirin.

~~b. No cirrhosis, will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or~~

~~c.a. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.~~

d. Genotype 3

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks~~ and documentation has been provided showing that the recipient is unable to receive peginterferon~~; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing ~~that~~ the recipient is unable to take ribavirin.~~ and showing the recipient is unable to receive peginterferon.~~

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy), documentation is provided showing that the recipient is unable to receive peginterferon and must meet one of the following:

   a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

   b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.~~; or~~

   ~~c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.~~

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy), documentation is provided that the recipient is unable to receive peginterferon and must meet one of the following:

   a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

   b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks.

6. Olysio® (simeprevir) (Initial Request)

   a. The requested dose is 150 mg (one capsule) daily.

   b. Genotype 1a

      1. The recipient is treatment-naïve and must meet one of the following:

         a. No cirrhosis, will be treated with Sovaldi and ribavirin and the requested duration is 12 weeks; or

         ~~b. No cirrhosis, will be treated with Sovaldi, the requested duration is 12 weeks, and documentation has been provided showing that the recipient is unable to take ribavirin; or~~

         ~~c.~~b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks, ~~and~~ the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~d.~~c. Compensated cirrhosis (CTP class A) will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, ~~and~~ documentation is~~has been~~ provided showing that the recipient is unable to take ribavirin and documentation is provided why the recipient cannont use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin, the requested duration is 24 weeks and the recipient is negative for the Q80K polymorphism; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism and documentation has been provided showing that the recipient is unable to take ribavirin.

c. Genotype 1b

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Sovaldi and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Sovaldi and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Sovaldi, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

7. Sovaldi® (sofosbuvir) (Initial Requests)

a. The requested dose is 400 mg daily.

b. Genotype 1

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza ~~and ribavirin~~ and the requested duration is 12 weeks; or

~~b. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing the recipient is unable to take ribavirin; or~~

~~c.~~b. No cirrhosis, ~~genotype 1a,~~ will be treated with Olysio ~~and ribavirin,~~ and the requested duration is 12 weeks; or

~~d. No cirrhosis, genotype 1a, will be treated with Olysio, the requested duration is 12 weeks, and documentation has been provided showing the recipient is unable to take ribavirin; or~~

~~e. No cirrhosis, genotype 1b, will be treated with Olysio, and the requested duration is 12 weeks; or~~

~~f. Compensated cirrhosis (CTP class A), will be treated with Daklinza+ ribavirin and the requested duration is 12 weeks; or~~

~~g.~~c. Compensated cirrhosis (CTP class A), will be treated with Daklinza + ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~h.~~d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, ~~and~~ documentation ~~has been~~ is provided showing the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~i.~~e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks, ~~and~~ the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~j.~~f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, ~~and~~ documentation ~~has been~~ is provided showing the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~k.~~g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~l.~~h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, ~~and~~ documentation has been provided that the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Olysio and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, requested duration is 24 weeks, ~~and~~ documentation is provided showing that the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen ; or

e. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio and ribavirin, the requested duration is 24 weeks ~~and~~ the recipient is negative for the Q80K polymorphism and documentation is provided why the recipient cannot use a guideline-recommended regimen ; or

f. Compensated cirrhosis (CTP class A), genotype 1a, will be treated with Olysio, the requested duration is 24 weeks, the recipient is negative for the Q80K polymorphism, ~~and~~ documentation ~~has been~~ is provided showing that the recipient is unable to take ribavirin and

documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~f.~~g. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~g.~~h. Compensated cirrhosis (CTP class A), genotype 1b, will be treated with Olysio, the requested duration is 24 weeks, ~~and~~ documentation ~~has been~~is provided showing that the recipient is unable to take ribavirin and documentation is provided why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor)~~, has had no prior treatment with an NS5A polymerase inhibitor (e.g, daclatasvir, ledipasvir, ombitasvir)~~ and must meet one of the following:

a. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin and the requested duration is 24 weeks; or

c. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to take ribavirin.

c. Genotype 2

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks ~~and documentation has been provided showing that the recipient is unable to take ribavirin~~; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or

~~d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 12 weeks and documentation has been provided showing that the recipient is unable to take ribavirin; or~~

~~e.~~d. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is ~~24~~ 16 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

   a. No cirrhosis, will be treated with ribavirin and the requested duration is ~~16~~ 12 weeks; or

   ~~b. No cirrhosis, will be treated with ribavirin and peginterferon, the requested duration is 12 weeks; or~~

   b. No cirrhosis, will be treated with Daklinza, the requested duration is 12 weeks and documentation is provided showing the recipient is unable to take ribavirin.

   c. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks; or

   d. Compensated cirrhosis (CTP class A), will be treated with ribavirin and the requested duration is 16 weeks to 24 weeks, and documentation is provided showing the recipient is unable to take ribavirin; or

   e. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon, ~~and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin dual therapy) and must meet one of the following:

   a. No cirrhosis, will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing the recipient is unable to receive peginterferon; or

   b. No cirrhosis, will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin and documentation has been provided showing that the recipient is unable to receive peginterferon; or

   c. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to receive peginterferon; or

e. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks, and documentation is provided showing the recipient is unable to take peginterferon and ribavirin.

~~e.~~f. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks.

d. Genotype 3

1. The recipient is treatment-naive and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 24 weeks and documentation ~~has been provided showing that the recipient is unable to receive peginterferon~~ is provided why the recipient cannot use a guideline-recommended regimen; or

c. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin and peginterferon and the requested duration is 12 weeks; or

e. Compensated cirrhosis (CTP class A) will be treated with ribavirin, the requested duration is 24 weeks ~~and documentation has been provided the recipient is unable to receive peginterferon~~ and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

f. Compensated cirrhosis (CTP class A) will be treated with Daklinza and ribavirin, the requested duration is 24 weeks ~~and documentation has been provided showing that the recipient is unable to receive peginterferon~~; or

g. Compensated cirrhosis (CTP class A) will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin. ~~and showing the recipient is unable to receive peginterferon.~~

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and the requested duration is 12 weeks; or

c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.~~; or~~

~~e. Compensated cirrhosis (CTP class A), will be treated with Daklinza, the requested duration is 24 weeks and documentation has been provided showing that the recipient is unable to take ribavirin.~~

3. The recipient is treatment-experienced (failed Sovaldi + ribavirin therapy dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

b. No cirrhosis, will be treated with Daklinza and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon; or

c. Compensated cirrhosis (CTP class A), will be treated with peginterferon and ribavirin and the requested duration is 12 weeks; or

d. Compensated cirrhosis (CTP class A), will be treated with Daklinza and ribavirin, ~~and~~ the requested duration is 24 weeks and documentation is provided showing the recipient is unable to take peginterferon.

e. Genotype 4

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon, ~~and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or~~

~~c.~~b. Compensated ~~C~~cirrhosis(CPT class A)~~,~~ will be treated with ribavirin and peginterferon~~, and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~d. Cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks.~~

2. The recipient is treatment- experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon~~, and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

~~b. No cirrhosis, will be treated with ribavirin and the requested duration is 24 weeks; or~~

~~c. Cirrhosis, will be treated with ribavirin and peginterferon, and the requested duration is 12 weeks;~~

~~d.~~b. Compensated ~~C~~cirrhosis (CPT class A)~~,~~ will be treated with ribavirin, ~~and~~ the requested duration is 24 weeks documentation is provided why the recipient cannot take peginerferon and documentation is provided why the recipient cannot use a guideline-recommended regimen.

f. Genotype 5, 6

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon and the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

b. Compensated ~~C~~cirrhosis (CPT class A)~~,~~ will be treated with ribavirin and peginterferon~~, and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon alfa + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin and peginterferon~~, and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

b. Compensated ~~C~~cirrhosis (CPT class A)~~,~~ will be treated with ribavirin and peginterferon~~, and~~ the requested duration is 12 weeks and documentation is provided why the recipient cannot use a guideline-recommended regimen.

8. Zepatier® (elbasvir and grazoprevir)

a. The requested dose is one tablet (50/100 mg) daily.

b. Genotype 1a

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CPT class A), requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected and documentation is provided why the recipient cannot use a guideline-recommended regimen.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected, and documentation is provided why the recipient cannot use a guideline-recommended regimen; or

c. Compensated cirrhosis (CTP class A), requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected, and documentation is provided why the recipient cannot use a guideline-recommended regimen.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks, and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

c. Genotype 1b

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A) and the requested duration is 12 weeks.

3. The recipient is treatment-experienced (failed peginterferon + ribavirin + NS3 protease inhibitor) and must meet one of the following:

a. No cirrhosis, will be treated with ribavirin, the requested duration is 12 weeks and there are no baseline NS5A RAVs for elbasvir detected; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks~~,~~ and baseline NS5A RAVs for elbasvir have been detected; or

c. Compensated cirrhosis (CTP class A), will be treated with ribavirin, requested duration is 12 weeks~~,~~ and there are no baseline NS5A RAVs for elbasvir detected; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks, baseline NS5A RAVs for elbasvir have been detected.

d. Genotype 4

1. The recipient is treatment-naïve and must meet one of the following:

a. No cirrhosis and the requested duration is 12 weeks; or

b. Compensated cirrhosis (CTP class A), and the requested duration is 12 weeks.

2. The recipient is treatment-experienced (failed peginterferon + ribavirin dual therapy) and must meet one of the following:

a. No cirrhosis, the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic response to peginterferon + ribavirin dual therapy; or

b. No cirrhosis, will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy; or

c. Compensated cirrhosis (CTP class A), the requested duration is 12 weeks and documentation is provided showing the recipient experienced virologic relapse to peginterferon + ribavirin dual therapy; or

d. Compensated cirrhosis (CTP class A), will be treated with ribavirin, the requested duration is 16 weeks and documentation has been provided showing the recipient experienced on-treatment virologic failure to peginterferon + ribavirin dual therapy.

~~8.~~9. Recipients who have received previous therapy with an NS5A inhibitor (e.g., daclatasvir, ledipasvir, ombitasvir) or combination therapy with sofosbuvir + simeprevir.

~~a. Genotype 1~~

a. The recipient must meet one of the following:

1. The recipient has cirrhosis; or

2. Documentation includes the clinical rationale for urgent retreatment.

b. Testing for resistance-associated variants (RAVs) have been done and results have been provided.

c. The requested regimen does not include agents in which RAVs have developed.

d. The requested regimen includes ribavirin or documentation has been provided that ribavirin is contraindicated.

~~a. No NS5A RAVs detected: Harvoni + ribavirin ± peginterferon x 24 weeks.~~

~~b. NS5A RAVs detected, no NS3 RAVS detected: Olysio + Sovaldi + ribavirin ± peginterferon x 24 weeks.~~

~~9.~~10. For requests for recertification (for treatment beyond 12 weeks), the recipient must meet all of the following:

a. Laboratory results for HCV RNA viral load at week four and week six (if applicable) have been submitted with the PA request; and

b. The recipient's HCV viral load must meet one of the following:

a. Undetectable HCV RNA viral load week four; or

b. Detectable HCV RNA viral load at treatment week four and HCV RNA increased by ≤ 10-fold (≤1 $\log_{10}$ IU/mL) on repeat testing at treatment week six (or thereafter).

c. And, the recipient is compliant on all drugs in the treatment regimen.

~~10.~~11. Prior Authorization Guidelines:

a. Prior authorization approval will be for a maximum of 12 weeks (unless the requested regimen is less than 12 weeks long or the remaining duration of therapy is less than 12 weeks).

b. The initial prescription will be limited to a 14-day supply; subsequent refills can be up to 34 days.

WW. Irritable-Bowel Syndrome Agents~~Viberzi® (eluxadoline)~~

Therapeutic Class: Irritable-Bowel Syndrome Agents~~μ-opioid receptor agonist/σ-opioid receptor antagonist/κ-receptor agonist~~
Last Reviewed by the DUR Board: ~~April 28, 2016~~July 28, 2016
Viberzi® last reviewed April 28, 2016

Irritable-Bowel Syndrom Agents~~Viberzi® (eluxadoline) is~~ are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. Approval will be given if the following criteria are met and documented:

1. The recipient is 18 years of age or older; and

2. The requested agent is being prescribed based on FDA approved guidelines; and

a. For requests for a diagnosis of Irritable-Bowel Syndrome with Constipation (IBS-C):

1. For requests for lubiprostone, the recipient must be female.

2. The requested dose is appropriate based on indication and age.

a. Linaclotide: 145 μg daily.

b. Lubiprostone: 290 μm daily.

b. For requests for a diagnosis of Irritable-Bowel Syndrome with Diarrhea (IBS-D):

1. The medication is being prescribed by or in consultation with a gastroenterologist, and

2. The requested dose is appropriate based on indication and age.

a. Alosetron: 0.5 mg twice daily or 1 mg twice daily.

b. Eluxadoline: 75 mg twice daily or 100 mg twice daily.

c. Rifaximin: 550 mg three times a day for 14 days.

~~1. Approval for Viberzi® (eluxadoline) will be given if all the following criteria are met and documented:~~

~~a. The recipient has a diagnosis of irritable bowel syndrome with diarrhea (IBS-D); and~~

~~b. The recipient is 18 years of age or older; and~~

~~c. The requested agent is prescribed by or in consultation with a gastroenterologist; and~~

~~d. The requested dose is 75 mg twice daily or 100 mg twice daily; and~~

~~e. One of the following is met:~~

~~1. The recipient has had an inadequate response or adverse reaction to one of the following: loperamide, diphenoxylate/atropine, bile acid sequestrants (cholestyramine, colestipol, colesevelam), tricyclic antidepressants (TCAs), or selective serotonin reuptake inhibitors (SSRIs); or~~

~~2. The recipient has a contraindication to all of the alternatives noted above.~~

2. Prior Authorization Guidelines

a. Prior authorization approval will be ~~for one year~~given for an appropriate length of therapy based on the requested agent and diagnosis, not to exceed one year.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx

YY. ~~RESERVED~~GnRH Analogs

Therapeutic Class: GnRH Analogs
Last Reviewed by the DUR Board: July 28, 2016

GnRH Analogs are subject to prior authorization and quantity limits based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board. Refer to the Nevada Medicaid and Check Up Pharmacy Manual for specific quantity limits.

1. Coverage and Limitations

a. This prior authorization criteria only applies to recipients who are under 18 years of age. Approval of Lupron® (leuprolide) will be given if all the following criteria, per individual diagnosis, are met and documented:

1. The recipient has a diagnosis of idiopathic or neurogenic central precocious puberty (CPP), and

a. The requested dose and frequency is based on FDA-approved guidelines, and

b. The medication is being prescribed by or in consultation with a pediatric endocrinologist, and

c. There is an onset of secondary sex characteristics before age 8 years (females) or 9 years (males), and

d. The recipient is currently less than 11 years of age (females) or 12 years of age (males).

2. The recipient has a diagnosis of of endometriosis, and

a. The requested dose and frequency is based on FDA-approved guidelines, and

b. The recipient has had an inadequate response, adverse reaction or contraindication to an NSAID, and

c. The recipient has had an inadequate response, adverse reaction or contraindication to a hormonal contraceptive.

3. The recipient has a diagnosis of uterine liomyomata (fibroids), and

a. The requested dose and frequency is based on FDA-approved guidelines, and

b. The recipient is symptomatic, and

c. Documentation has been submitted of the anticipated surgery date (or notation that surgery is planned once the fibroids shrink), or clinical rational why surgical intervention is not required.

4. The recipient has a diagnosis of prostate cancer, and

a. The requested dose and frequency is based on FDA-approved guidelines.

2. Prior Authorization Guidelines

a. Prior authorization approval will be given for an appropriate length based on the diagnosis, unless the prescriber indicates a shorter duration of approval.

1. CPP: 1 year, or until the member reaches the age of 11 years (female) or 12 years (male).

2. Endometriosis: 1 year.

3. Uterine Leiomyomata (fibroids): 1 month or until the time of the documented surgery (maximum of 3 months).

4. Prostate Cancer: 1 year.

b. Prior Authorization forms are available at: http://www.medicaid.nv.gov/providers/rx/rxforms.aspx