

STATE OF NEVADA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUSINESS ASSOCIATE ADDENDUM

BETWEEN

The Division of Health Care Financing and Policy

Herein after referred to as the "Covered Entity"

and

(Enter Business Name)

Herein after referred to as the "Business Associate"

PURPOSE. In order to comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Public Law 104-191, and the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, Public Law 111-5 this Addendum is hereby added and made part of the Contract between the Covered Entity and the Business Associate. This Addendum establishes the obligations of the Business Associate and the Covered Entity as well as the permitted uses and disclosures by the Business Associate of protected health information it may possess by reason of the Contract. The Covered Entity and the Business Associate shall protect the privacy and provide for the security of protected health information disclosed to the Business Associate pursuant to the Contract and in compliance with HIPAA, the HITECH Act, and regulation promulgated there under by the U.S. Department of Health and Human Services ("HIPAA Regulations") and other applicable laws.

WHEREAS, the Business Associate will provide certain services to the Covered Entity, and, pursuant to such arrangement, the Business Associate is considered a business associate of the Covered Entity as defined in HIPAA Regulations; and

WHEREAS, the Business Associate may have access to and/or create, receive, maintain or transmit certain protected health information from or on behalf of the Covered Entity, in fulfilling its responsibilities under such arrangement; and

WHEREAS, HIPAA Regulations require the Covered Entity to enter into a contract containing specific requirements of the Business Associate prior to the disclosure of protected health information; and

THEREFORE, in consideration of the mutual obligations below and the exchange of information pursuant to this Addendum and to protect the interests of both Parties, the Parties agree to all provisions of this Addendum.

I. **DEFINITIONS.** The following terms in this Addendum shall have the same meaning as those terms in the HIPAA Regulations: Breach, Data Aggregation, Designated Record Set, Disclosure, Electronic Health Record, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required by Law, Secretary, Subcontractor, Unsecured Protected Health Information, and Use.

1. **Business Associate** shall mean the name of the organization or entity listed above and shall have the meaning given to the term under the Privacy and Security Rule and the HITECH Act. For full definition refer to 45 CFR 160.103.
2. **Contract** shall refer to this Addendum and that particular Contract to which this Addendum is made a part.
3. **Covered Entity** shall mean the name of the Division listed above and shall have the meaning given to such term under the Privacy Rule and the Security Rule, including, but not limited to 45 CFR 160.103.

4. **Parties** shall mean the Business Associate and the Covered Entity.

II. OBLIGATIONS OF THE BUSINESS ASSOCIATE

1. **Access to Protected Health Information.** The Business Associate will provide, as directed by the Covered Entity or an individual, access to inspect or obtain a copy of protected health information about the individual that is maintained in a designated record set by the Business Associate or its agents or subcontractors, in order to meet the requirements of HIPAA Regulations. If the Business Associate maintains an electronic health record, the Business Associate, its agents or subcontractors shall provide such information in electronic format to enable the Covered Entity to fulfill its obligations under HIPAA Regulations.
2. **Access to Records.** The Business Associate shall make its internal practices, books and records relating to the use and disclosure of protected health information available to the Covered Entity and to the Secretary for purposes of determining Business Associate's compliance with HIPAA Regulations.
3. **Accounting of Disclosures.** Upon request, the Business Associate and its agents or subcontractors shall make available to the Covered Entity or the individual information required to provide an accounting of disclosures in accordance with HIPAA Regulations.
4. **Agents and Subcontractors.** The Business Associate must ensure all agents and subcontractors that create, receive, maintain, or transmit protected health information on behalf of the Business Associate agree in writing to the same restrictions and conditions that apply to the Business Associate with respect to such information. The Business Associate must implement and maintain sanctions against agents and subcontractors that violate such restrictions and conditions and shall mitigate the effects of any such violation as outlined under HIPAA Regulations.
5. **Amendment of Protected Health Information.** The Business Associate will make available protected health information for amendment and incorporate any amendments in the designated record set maintained by the Business Associate or its agents or subcontractors, as directed by the Covered Entity or an individual, in order to meet the requirements of HIPAA Regulations.
6. **Audits, Investigations, and Enforcement.** If the data provided or created through the execution of the Contract becomes the subject of an audit, compliance review, or complaint investigation by the Office of Civil Rights or any other federal or state oversight agency, the Business Associate shall notify the Covered Entity immediately and provide the Covered Entity with a copy of any protected health information that the Business Associate provides to the Secretary or other federal or state oversight agency concurrently, to the extent that it is permitted to do so by law. The Business Associate and individuals associated with the Business Associate are solely responsible for all civil and criminal penalties assessed as a result of an audit, breach or violation of HIPAA Regulations.
7. **Breach or Other Improper Access, Use or Disclosure Reporting.** The Business Associate must report to the Covered Entity, in writing, any access, use or disclosure of protected health information not permitted by the Contract, Addendum or HIPAA Regulations by Business Associate or its agents or subcontractors. The Covered Entity must be notified immediately upon discovery or the first day such breach or suspected breach is known to the Business Associate or by exercising reasonable diligence would have been known by the Business Associate in accordance with HIPAA Regulations. In the event of a breach or suspected breach of protected health information, the report to the Covered Entity must be in writing and include the following: a brief description of the incident; the date of the incident; the date the incident was discovered by the Business Associate; a thorough description of the unsecured protected health information that was involved in the incident; the number of individuals whose protected health information was involved in the incident; and the steps the Business Associate or its agent or subcontractor is taking to investigate the incident and to protect against further incidents. The Covered Entity will determine if a breach of unsecured protected health information has occurred and will notify the Business Associate of the determination. If a breach of unsecured protected health information is determined, the Business Associate must take prompt corrective action to cure any such deficiencies and mitigate any significant harm that may have occurred to individual(s) whose information was disclosed inappropriately.

8. **Breach Notification Requirements.** If the Covered Entity determines a breach of unsecured protected health information by the Business Associate, or its agents or subcontractors has occurred, the Business Associate will be responsible for notifying the individuals whose unsecured protected health information was breached in accordance with HIPAA Regulations. The Business Associate must provide evidence to the Covered Entity that appropriate notifications to individuals and/or media, when necessary, as specified in HIPAA Regulations has occurred. The Business Associate is responsible for all costs associated with notification to individuals, the media or others as well as costs associated with mitigating future breaches. The Business Associate must notify the Secretary of all breaches in accordance with HIPAA Regulations and must provide the Covered Entity with a copy of all notifications made to the Secretary.
- ~~9. **Breach Pattern or Practice by Covered Entity.** Pursuant to HIPAA Regulations, if the Business Associate knows of a pattern of activity or practice of the Covered Entity that constitutes a material breach or violation of the Covered Entity's obligations under the Contract or Addendum, the Business Associate must immediately report the problem to the Secretary.~~
- 10.9. **Data Ownership. The Business Associate acknowledges** that the Business Associate or its agents or subcontractors have no ownership rights with respect to the protected health information it creates, receives or maintains, or otherwise holds, transmits, uses or discloses.
- 11.10. **Litigation or Administrative Proceedings.** The Business Associate shall make itself, any subcontractors, employees, or agents assisting the Business Associate in the performance of its obligations under the Contract or Addendum, available to the Covered Entity, at no cost to the Covered Entity, to testify as witnesses, or otherwise, in the event litigation or administrative proceedings are commenced against the Covered Entity, its administrators or workforce members upon a claimed violation by Business Associate of HIPAA Regulations or other laws relating to security and privacy.
- 12.11. **Minimum Necessary.** The Business Associate and its agents and subcontractors shall request, use and disclose only the minimum amount of protected health information necessary to accomplish the purpose of the request, use or disclosure in accordance with HIPAA Regulations.
- 13.12. **Policies and Procedures.** The Business Associate must adopt written privacy and security policies and procedures and documentation standards to meet the requirements of HIPAA Regulations.
- 14.13. **Privacy and Security Officer(s).** The Business Associate must appoint Privacy and Security Officer(s) whose responsibilities shall include: monitoring the Privacy and Security compliance of the Business Associate; development and implementation of the Business Associate's HIPAA Privacy and Security policies and procedures; establishment of Privacy and Security training programs; and development and implementation of an incident risk assessment and response plan in the event the Business Associate sustains a breach or suspected breach of protected health information.
- 15.14. **Safeguards.** The Business Associate must implement safeguards as necessary to protect the confidentiality, integrity and availability of the protected health information the Business Associate creates, receives, maintains, or otherwise holds, transmits, uses or discloses on behalf of the Covered Entity. Safeguards must include administrative safeguards (e.g., risk analysis and designation of security official), physical safeguards (e.g., facility access controls and workstation security), and technical safeguards (e.g., access controls and audit controls) to the confidentiality, integrity and availability of the protected health information, in accordance with HIPAA Regulations. Technical safeguards must meet the standards set forth by the guidelines of the National Institute of Standards and Technology (NIST). The Business Associate agrees to only use or disclose protected health information as provided for by the Contract and Addendum and to mitigate, to the extent practicable, any harmful effect that is known to the Business Associate, of a use or disclosure, in violation of the requirements of this Addendum as outlined in HIPAA Regulations.
- 16.15. **Training.** The Business Associate must train all members of its workforce on the policies and procedures associated with safeguarding protected health information. This includes, at a minimum, training that covers the technical, physical and administrative safeguards needed to prevent inappropriate uses or disclosures of protected health information; training to prevent any intentional or unintentional use or disclosure that is a violation of HIPAA Regulations; and training that emphasizes the criminal and civil penalties related to HIPAA breaches or inappropriate uses

or disclosures of protected health information. Workforce training of new employees must be completed within 30 days of the date of hire and all employees must be trained at least annually. The Business Associate must maintain written records for a period of six years. These records must document each employee that received training and the date the training was provided or received.

47.16. Use and Disclosure of Protected Health Information. The Business Associate must not use or further disclose protected health information other than as permitted or required by the Contract or as required by law. The Business Associate must not use or further disclose protected health information in a manner that would violate the requirements of HIPAA Regulations.

III. PERMITTED AND PROHIBITED USES AND DISCLOSURES BY THE BUSINESS ASSOCIATE

The Business Associate agrees to these general use and disclosure provisions:

1. Permitted Uses and Disclosures:

- a. Except as otherwise limited in this Addendum, the Business Associate may use or disclose protected health information to perform functions, activities, or services for, or on behalf of, the Covered Entity as specified in the Contract, provided that such use or disclosure would not violate HIPAA Regulations, if done by the Covered Entity.
- b. Except as otherwise limited in this Addendum, the Business Associate may use or disclose protected health information received by the Business Associate in its capacity as a Business Associate of the Covered Entity, as necessary, for the proper management and administration of the Business Associate, to carry out the legal responsibilities of the Business Associate, as required by law or for data aggregation purposes in accordance with HIPAA Regulations.
- c. Except as otherwise limited by this Addendum, if the Business Associate discloses protected health information to a third party, the Business Associate must obtain, prior to making such disclosure, reasonable written assurances from the third party that such protected health information will be held confidential pursuant to this Addendum and only disclosed as required by law or for the purposes for which it was disclosed to the third party. The written agreement from the third party must include requirements to immediately notify the Business Associate of any breaches of confidentiality of protected health information to the extent it has obtained knowledge of such breach.
- d. The Business Associate may use or disclose protected health information to report violations of law to appropriate federal and state authorities, consistent with HIPAA Regulations.

2. Prohibited Uses and Disclosures:

- a. Except as otherwise limited in this Addendum, the Business Associate shall not disclose protected health information to a health plan for payment or health care operations purposes if the patient has required this special restriction, and has paid out of pocket in full for the health care item or service to which the protected health information relates in accordance with HIPAA Regulations.
- b. The Business Associate shall not directly or indirectly receive remuneration in exchange for any protected health information, unless the Covered Entity obtained a valid authorization, in accordance with HIPAA Regulations that includes a specification that protected health information can be exchanged for remuneration.

IV. OBLIGATIONS OF THE COVERED ENTITY

1. The Covered Entity will inform the Business Associate of any limitations in the Covered Entity's Notice of Privacy Practices in accordance with HIPAA Regulations, to the extent that such limitation may affect the Business Associate's use or disclosure of protected health information.
2. The Covered Entity will inform the Business Associate of any changes in, or revocation of, permission by an individual to use or disclose protected health information, to the extent that such changes may affect the Business Associate's use or disclosure of protected health information.
3. The Covered Entity will inform the Business Associate of any restriction to the use or disclosure of protected health information that the Covered Entity has agreed to in accordance with HIPAA

Regulations, to the extent that such restriction may affect the Business Associate's use or disclosure of protected health information.

4. Except in the event of lawful data aggregation or management and administrative activities, the Covered Entity shall not request the Business Associate to use or disclose protected health information in any manner that would not be permissible under HIPAA Regulations, if done by the Covered Entity.

V. TERM AND TERMINATION

1. **Effect of Termination:**

- a. Except as provided in paragraph (b) of this section, upon termination of this Addendum, for any reason, the Business Associate will return or destroy all protected health information received from the Covered Entity or created, maintained, or received by the Business Associate on behalf of the Covered Entity that the Business Associate still maintains in any form and the Business Associate will retain no copies of such information.
 - b. If the Business Associate determines that returning or destroying the protected health information is not feasible, the Business Associate will provide to the Covered Entity notification of the conditions that make return or destruction infeasible. Upon a mutual determination that return or destruction of protected health information is infeasible, the Business Associate shall extend the protections of this Addendum to such protected health information and limit further uses and disclosures of such protected health information to those purposes that make return or destruction infeasible, for so long as the Business Associate maintains such protected health information.
 - c. These termination provisions will apply to protected health information that is in the possession of subcontractors, agents or employees of the Business Associate.
2. **Term.** The Term of this Addendum shall commence as of the effective date of this Addendum herein and shall extend beyond the termination of the contract and shall terminate when all the protected health information provided by the Covered Entity to the Business Associate, or accessed, maintained, created, retained, modified, recorded, stored or otherwise held, transmitted, used or disclosed by the Business Associate on behalf of the Covered Entity, is destroyed or returned to the Covered Entity, or if it is not feasible to return or destroy the protected health information, protections are extended to such information, in accordance with the termination.
 3. **Termination for Breach of Contract.** The Business Associate agrees that the Covered Entity may immediately terminate the Contract if the Covered Entity determines that the Business Associate has violated a material part of this Addendum.

VI. MISCELLANEOUS

1. **Amendment.** The parties agree to take such action as is necessary to amend this Addendum from time to time for the Covered Entity to comply with all the requirements of HIPAA Regulations.
2. **Clarification.** This Addendum references the requirements of HIPAA Regulations, as well as amendments and/or provisions that are currently in place and any that may be forthcoming.
3. **Indemnification.** Each party will indemnify and hold harmless the other party to this Addendum from and against all claims, losses, liabilities, costs and other expenses incurred as a result of, or arising directly or indirectly out of or in conjunction with:
 - a. Any misrepresentation, breach of warranty or non-fulfillment of any undertaking on the part of the party under this Addendum; and
 - b. Any claims, demands, awards, judgments, actions, and proceedings made by any person or organization arising out of or in any way connected with the party's performance under this Addendum.
4. **Interpretation.** The provisions of this Addendum shall prevail over any provisions in the Contract that any conflict or appear inconsistent with any provision in this Addendum. This Addendum and the Contract shall be interpreted as broadly as necessary to implement and comply with HIPAA Regulations. The parties agree that any ambiguity in this Addendum shall be resolved to permit the Covered Entity and the Business Associate to comply with HIPAA Regulations.

5. **Regulatory Reference.** A reference in this Addendum to HIPAA Regulations means the sections as in effect or as amended.
6. **Survival.** The respective rights and obligations of Business Associate under Effect of Termination of this Addendum shall survive the termination of this Addendum.

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IN WITNESS WHEREOF, the Business Associate and the Covered Entity have agreed to the terms of the above written agreement as of the effective date set forth below.

COVERED ENTITY

Division of Health Care Financing and Policy

1100 E. William Street, Suite 101

Carson City, NV 89701

(775) 684-3676

(775) 687-3893

(Authorized Signature)

Laurie Squartsoff

Administrator

(Date)

BUSINESS ASSOCIATE

(Business Name)

(Business Address)

(City, State and Zip Code)

(Business Phone Number)

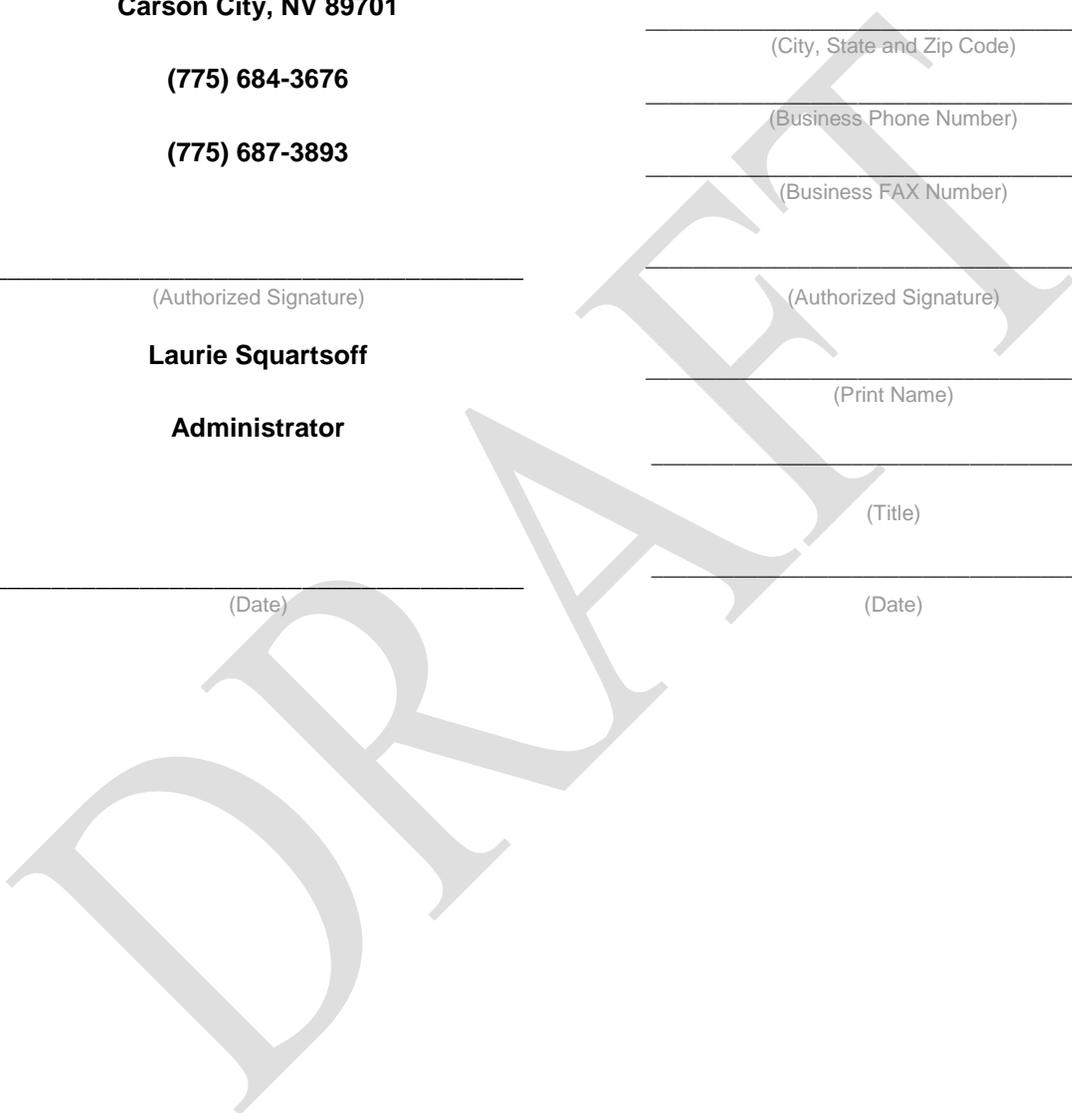
(Business FAX Number)

(Authorized Signature)

(Print Name)

(Title)

(Date)



MEDICAID SERVICES MANUAL
TRANSMITTAL LETTER

September 3, 2015

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: TAMMY MOFFITT, CHIEF OF PROGRAM INTEGRITY

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 200 - HOSPITAL SERVICES

BACKGROUND AND EXPLANATION

Revisions to Medicaid Services Manual (MSM) Chapter 200 are being proposed to specify that providers must ensure a valid sterilization consent form meeting all federal requirements is obtained prior to performing a sterilization procedure, deny coverage of the one inpatient day during which sterilization is performed without a valid sterilization consent form, cover medically necessary inpatient days within the same episode of care that are not the day the sterilization procedure was performed without a valid prior authorization, and define the term, episode of care. A revision was also made to clarify coverage of non-emergency services provided in an emergency room.

These changes are effective September 4, 2015.

MATERIAL TRANSMITTED	MATERIAL SUPERSEDED
CL 29367 CHAPTER 200 - HOSPITAL SERVICES	MTL 05/15 CHAPTER 200 - HOSPITAL SERVICES

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
203.1B.16	Provider Responsibilities	Revised policy to: specify providers must ensure a valid sterilization consent form meeting all federal requirements is obtained prior to performing a sterilization procedure; deny coverage of the one inpatient day during which sterilization is performed without a valid sterilization consent form; cover medically necessary inpatient days within the same episode of care that are not the day the sterilization procedure was performed without a valid PA, and define episode of care.
203.4A.2	Coverage and Limitations	Clarified coverage of non-emergency services provided in an emergency room for recipients with full Medicaid eligibility.

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2. last longer than eight hours or involving an overnight stay from a Medical Rehabilitation hospital
- c. A leave of absence from an acute inpatient hospital is not covered if a recipient does not return to the hospital by midnight of the day the leave of absence began (a reserved bed).
- d. For a therapeutic leave of absence, the following information must be documented in a recipient's medical record:
 1. A physician's order specifying the number of hours for the pass;
 2. The medically appropriate reason for the pass prior to issuance of the pass; and
 3. An evaluation of the therapeutic effectiveness of the pass when the recipient returns.

203.1B PROVIDER RESPONSIBILITIES

1. Patient Liability

- a. **Determination:** Patient Liability (PL) is determined by eligibility personnel in the local Division of Welfare and Supportive Services (DWSS) District Office. The hospital is notified of PL on the Notice of Decision (NOD) form. For questions regarding PL, please contact the local DWSS District Office.
- b. **Collection:** When a case is approved or PL changes, the recipient, facility and fiscal agent (and authorized representative, where appropriate) are notified of the amount and effective date. Collection of PL is the facility's responsibility.
 1. If the application is approved, the facility is sent a NOD indicating the amount of PL due and the effective date. The recipient and the fiscal agent are also notified. If eligibility is retroactive and the date of decision on months of eligibility more than 24 months from month of decision, a Medicaid Case Status Form (2214-EM) will be sent to the medical facility.
 2. PL for new approvals is effective the first month of eligibility for Medicaid. When a recipient's income changes, PL is adjusted beginning with the month of the change.
 3. The monthly PL is deducted from the initial claim received by the QIO-like vendor from a qualified facility. There is no prorating of PL for recipients transferring facilities within the month.

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4. If a recipient expires mid-month, the DWSS prorates PL as in number 3 above. The facility will be sent a notice indicating the adjusted PL amount.
5. No PL is taken from Medicaid recipients during periods of Medicare coverage. Beginning with the first non-Medicare covered day, hospitals must access PL at the Medicaid LOC and per diem rate for that hospital.

2. Conditions of Participation

a. To be enrolled with the DHCFP, providers must:

1. be in compliance with applicable licensure requirements.
2. be certified to participate in the Medicare program. Hospitals currently accredited by the Joint Commission or by the American Osteopathic Association (AOA) are deemed to meet all of the conditions of participation in Medicare. Centers for Medicare and Medicaid Services (CMS) makes the final determination of whether a hospital meets all Medicare criteria based on the recommendation of the state certifying agency (42 CFR Part 482).
3. have a Provider Contract with the DHCFP. Refer to Chapter 100, Section 102, Provider Enrollment.

b. Termination

The DHCFP may terminate a provider contract for failure of a hospital to adhere to the conditions of participation, reimbursement principles, standards of licensure, or to conform to federal, state, and local laws. Either party may terminate its agreement without cause at any time during the term of agreement by prior written notice to the other party.

Loss of Medicare certification results in concomitant loss of a Medicaid contract.

Refer to MSM, Chapter 100, for termination, lockout, suspension, exclusion, and non-renewal of Medicaid provider enrollment.

3. Utilization Review (UR)

Parts 456.100 through 456.145 of Section 42 CFR prescribe the requirements for a written UR plan for each hospital providing Medicaid services. The UR plan is deemed met for Medicare and Medicaid if a QIO-like vendor is conducting binding review.

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CFR 482.30 provides that hospitals participating in the Medicaid program must have in effect a UR program under a QIO-like or CMS has determined that the UR procedures established by the Medicaid program are superior to the procedures under the QIO-like vendor, and meet the UR plan requirements under 42 CFR 456.50 through 456.24

4. Quality Assurance - Hospital Medical Care Evaluation Studies

The purpose of hospital medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with recipient needs and professionally recognized standards of care. (CFR 456.141 to 456.145)

As part of the conditions of participation in the Medicaid Title XIX program, a minimum of one medical care evaluation study must be in progress at any time. Additionally, one study must be completed each year. The completed study must be submitted to the QIO-like vendor at the end of each calendar year along with the study in progress topic. (A report summarizing the study topics will be submitted to Nevada Medicaid by the QIO-like vendor.)

Hospitals may design and choose their own study topic or, at the request of Medicaid, perform a topic designed by Medicaid, and forward a copy of the completed study to the QIO-like vendor office within the specified time frames.

5. Civil Rights Compliance

As recipients of federal funding, hospitals must assure compliance with the provisions of Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973 (including HIV, AIDS and AIDS-related conditions), the Age Discrimination Act of 1975, and the Americans with Disabilities Act (ADA) of 1990.

6. Patient Self-Determination Act (Advance Directives) Compliance

Pursuant to the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), and federal regulations at 42 CFR 489.100, hospitals which participate in and receive funding for Medicare and/or Medicaid must comply with the Patient Self Determination Act (PSDA) of 1990, including Advance Directives. The DHC FP is responsible for monitoring/reviewing hospitals periodically to determine whether they are complying with federal and state advance directive requirements.

7. Form 3058 (Admit/Discharge/Death Notice)

All hospitals are required to submit Form 3058 to their local DWSS District Office whenever a hospital admission, discharge, or death occurs.

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Failure to submit this form could result in payment delay or denial. To obtain copies of Form 3058, please contact the local DWSS.

8. Patient Rights

Pursuant to 42 CFR 482.13, a hospital must protect and promote each patient's rights. Hospitals are also required to comply with Nevada Revised Statutes (NRS) 449.730 pertaining to patient's rights.

9. Claims for Denied Admissions

After having an inpatient service authorized by the QIO-like vendor, hospitals are not permitted to submit the claim to the fiscal agent as an outpatient service. The only exception to this is if an outpatient or non-inpatient related service was truly rendered prior to the inpatient admission order by the physician but the inpatient stay was denied by the QIO-like vendor (e.g., admit from ER or rollover from observation days).

10. Hospital Responsibilities for Services

Any hospital receiving authorization from the QIO-like vendor to admit and provide services for a recipient is responsible for the recipient's service and treatment needs. If a hospital does not have the proper or functional medical equipment or services, and must transfer a recipient temporarily to another hospital or other medical service provider (generally for only a portion of that day) for testing, evaluation, and/or treatment, it is the transferring hospital's responsibility to fund the particular services and transportation if necessary.

11. Admission Medical Record Documentation

a. Pre-Admission Authorization

The physician (or his/her staff) must obtain prior authorization from the QIO-like vendor for all non-emergency, elective, planned hospital procedures/admissions. Lack of a prior authorization for an elective procedure or admission results in an automatic denial which cannot be appealed. Reference Chapter 600.

Dental, oral and maxillofacial surgeons must also secure prior authorization from the DHCFP dental consultant to assure payment for the procedure. (Reference 203.1A.2.f.4) and Chapters 600 and 1000 regarding covered dental benefits.

b. Physician Certification

A physician's order, written prior to or at the time of admission, is required for all

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inpatient admissions. If a recipient applies for assistance while in the hospital, a physician's order for inpatient admission is required before reimbursement is authorized.

A physician, or physician's assistant or nurse practitioner acting within the scope of practice, as defined by state law and under the supervision of a physician, must re-certify for each applicant or recipient that inpatient services in a hospital are medically necessary. Re-certification must be made at least every 60 calendar days after the initial order. (42 CFR 456.60)

c. Plan of Care

Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the recipient must establish a written plan of care for each applicant or recipient. (42 CFR 456.80)

The plan of care must include:

1. diagnoses, symptoms, complaints, and complications indicating the need for admission;
2. a description of the functional level of the individual;
3. any orders for medications, treatments, restorative and rehabilitative services, activities, social services, diet;
4. plans for continuing care, as appropriate; and
5. plans for discharge, as appropriate.

12. Discharge Planning

- a. The hospital must designate separate, identifiable staff whose primary responsibility is discharge planning. The discharge planners must review all Medicaid admissions.
- b. Discharge planning activities must commence within 48 hours of admission (or up to 72 hours involving weekends) for every recipient.
- c. The discharge planner formulates and records a discharge plan. The plan must specify goals and resolution dates. All alternatives to NF placement must be explored (e.g., home health services, homemaker services, placement with family, subsidized housing, meals programs, group care, etc).

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- d. The discharge planner must coordinate the discharge plan with primary care staff, the family, the physician, the placement setting (if applicable) and the recipient.
- e. The planner must be aware of and identify the LOC or level of services necessary to maintain the recipient out of the hospital setting.
- f. The plan must be updated with changes in the recipient's condition.
- g. There must be documentation that immediate action is taken regarding discharge alternatives whenever a specific discharge intervention or placement effort fails.
- h. Evaluation and reevaluation of a recipients needs must be conducted as necessary during the discharge planning process.
- i. Documentation must be explicit, thorough and recorded on the date a service is provided. There must be documented evidence of frequent attempts by the provider to discharge the recipient to an alternative appropriate setting. The frequency of documentation will depend on the barriers to discharge.
- k. Failure of a hospital to have documented evidence of comprehensive discharge planning efforts will result in non-coverage of corresponding dates of service.
- j. Significant contacts with family, the recipient, and/or ancillary personnel must be documented in the medical record.
- k. The recipient's understanding of his/her condition and situation should be described.
- l. When a recipient requires transfer to a NF, the hospital must request a Pre-Admission Screening (PASRR) from the QIO-like vendor. Each nursing home contact must be recorded by the discharge planner. Reasons why nursing facilities refuse the placement must also be documented. Placement efforts need to be concentrated on those facilities capable of handling the recipient's needs. Resolution of the placement problem must be briefly described before the medical record is closed.
- m. A recipient's or recipient's family's or physician's refusal to cooperate with discharge planning efforts to either find or accept available appropriate placement at NF, RTC or other appropriate alternate setting must be documented in the recipient's medical record. Inpatient or administrative days are not reimbursed as of the date of the refusal.
- n. A discharge from the hospital is validated by a physician's discharge order. Any

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readmission following a discharge is treated as a new/separate admission, even if the readmission occurs within 24 hours of the discharge.

- o. As a condition of participation in the Medicare and Medicaid programs, hospitals must comply with all discharge planning requirements set forth in 42 CFR 482.43.

13. Financial Data and Reports

Providers must maintain sufficient financial records and statistical data for proper determination of costs payable under the DHCFFP program.

All providers shall permit any representative of the single state agency to examine the records and documents necessary to determine the proper amount of payments due. These records shall include, but are not limited to, provider ownership, organization, and operation; fiscal, medical, and other record keeping systems; federal income tax status; asset acquisition, lease, sale, or other action; franchise or management arrangements; patient service charge schedules; costs of operation; amounts of income received, by source and purpose; flow of funds and working capital; statistical and other reimbursement information.

14. Medicare/Medicaid Crossovers

Concurrent review is not conducted for Medicare/Medicaid crossover admissions unless acute days have been exhausted and/or there has been a termination of Medicare benefits and the recipient is at an acute or administrative LOC. Medicaid authorization is provided for acute and administrative days only.

A provider must:

- a. notify the QIO-like vendor whenever there is a reason to believe that Medicare coverage has been exhausted.
- b. attach a copy of the Medicare Explanation of Benefits (EOB) (if obtained from Medicare) or other supporting documentation that clearly indicates that acute care hospital days have been exhausted when requesting a QIO-like vendor review.
- c. obtain prior authorization from DHCFFP's QIO-like vendor in accordance with Section 203.1A.2.f.15.

QMB claims denied by Medicare are also denied by DHCFFP.

15. Maternity/Newborn Federal Length of Stay Requirements

A provider must allow a recipient receiving maternity care or a newborn infant receiving

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pediatric care to remain in the hospital for no less than 48 hours after a normal vaginal delivery or 96 hours after a cesarean section delivery except when an attending physician makes a decision to discharge a mother or newborn infant prior to these timeframes.

16. Sterilization Consent Form

Providers must ensure a valid sterilization consent form meeting all federal requirements is obtained prior to performing a sterilization procedure. Reference MSM Chapter 600, Attachment B, Sterilization Consent Form; and the QIO-like vendor's Sterilization and Abortion Policy under Provider, Billing Instructions, Billing Information for the specific procedures.

- a. An inpatient day during which sterilization is performed without a valid sterilization form is a non-covered service.
- b. Medically necessary inpatient days within the same episode of care, not including the day of the sterilization, may be reimbursed when the sterilization consent form was not obtained. An episode of care is defined as the admission date to date of discharge. All applicable coverage inpatient rules apply.

17. In-State or Out-of-State Hospital Transfers

a. Non Emergency Transfers

- 1. It is the responsibility of the transferring physician/facility to obtain prior authorization for nonemergent transfers between in-state and out-of-state facilities, prior to the transfer of the recipient and to give the authorization number to the receiving hospital.
- 2. A receiving hospital is responsible for verifying that the transferring hospital obtained prior authorization for a non emergency transfer, prior to agreeing to accept or admitting the recipient and prior to the transfer.

b. Emergency Transfers

A receiving hospital is responsible for obtaining authorization for an emergency transfer within one business day of the inpatient admission.

18. Admissions to Hospitals Without a Psychiatric Unit or Alcohol/Substance Abuse Treatment Unit

- a. Reference MSM Chapter 400, Mental Health and Alcohol/Substance Abuse Services.

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b. Long-Term Acute Care (LTAC) Hospital Services Policy

LTAC hospitals provide comprehensive long-term acute care designed for patients who have suffered an acute illness, injury or exacerbation of a disease process.

Most commonly, specialty or LTAC hospitals treat patients who require ventilator, wound care, or stroke-related services.

Inpatient specialty or LTAC services may be provided in either a freestanding specialty/long-term acute care hospital or a specialty/long-term acute unit of a general hospital.

Pain Management Services standing alone (e.g., relaxation techniques, stress management, coma stimulation, biofeedback) are not a DHCFP benefit.

203.3 SWING-BED SERVICES POLICY

Reference Chapter 200, Attachment A, Policy #02-04, Hospitals with Swing Beds.

203.4 OUTPATIENT HOSPITAL SERVICES POLICY

General Medical/Surgical Hospitals commonly provide several outpatient services, included but not limited to general, clinic, office, emergency room, ambulatory surgery center, and observation services.

203.4A COVERAGE AND LIMITATIONS

1. Outpatient hospital services provided by hospitals are subject to the same service limitations as other outpatient service providers. Providers must refer to Medicaid/DHCFP service manuals relevant to the specific services being provided. The following is a list of some of the chapters a hospital should reference:

- a. For physician, advanced practitioner of nursing, physician assistants, urgent care sites, and outpatient hospital clinic visits, refer to MSM Chapter 600.
- b. For radiologic services, refer to MSM Chapter 300.
- c. For pharmaceutical services, refer to MSM Chapter 1200.

This is not an all inclusive list. The MSM in its entirety needs to be reviewed.

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2. Emergency Room Services

Emergency services are defined as a case in which delay in treatment of more than 24 hours could result in severe pain, loss of life, limb, eyesight or hearing, injury to self or bodily harm to others.

Non-emergent services provided in an emergency room are a covered service for recipients with full Medicaid eligibility. Providers are expected to follow national coding guidelines by billing at the most appropriate level for any services provided in an emergency room setting.

Laboratory and radiological services ordered during the course of emergency room services (when it is an emergency diagnosis and not a clinic diagnosis) are payable without prior payment authorization.

Charges made for stat performance of laboratory or radiological procedures ordered during a hospital's normal operating hours in the applicable department are not a DHCFP benefit.

Patients requiring mental health services while in the emergency room may receive such services if medically appropriate, but must first be stabilized. Every effort must be made to transfer the patient to a psychiatric hospital or unit, accompanied by a physician's order. Authorization from the DHCFP's QIO-like vendor is also required.

3. Observation Services

Reference Chapter 200, Attachment A, Policy #02-05, Observation Services.

203.5 AMBULATORY SURGICAL SERVICES POLICY

Ambulatory Surgical Centers refers to freestanding or hospital based licensed ambulatory surgical units that can administer general anesthesia, monitor the recipient, provide postoperative care, and provide resuscitation as necessary. These recipients receive care in a facility operated primarily for performing surgical procedures on recipients expected to return safely home within 24 hours.

By contrast, physician office (MD-Office) services refers to a setting limited to use of local anesthesia, including private physician office, emergency room, urgent care centers, and clinic settings.

Observation/Medical short stay refers to the "ambulatory" recipient with a coexisting medical condition or some unforeseen medical situation who may remain in a hospital environment for an extended period. This extended stay, called observation or medical short stay can be used to

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TRANSMITTAL LETTER

August 13, 2015

TO: CUSTODIANS OF MEDICAID SERVICES MANUAL

FROM: TAMMY MOFFITT, CHIEF OF PROGRAM INTEGRITY

SUBJECT: MEDICAID SERVICES MANUAL CHANGES
CHAPTER 1200 - PRESCRIBED DRUGS

BACKGROUND AND EXPLANATION

The Drug Use Review (DUR) Board is a requirement of the Social Security Act (SSA) to identify and reduce fraud, abuse, overuse, and medically unnecessary care. The DUR Board also works to minimize drug interactions, drug-induced illness, and undesirable drug reactions in recipients.

Revised and new prior authorization criteria were approved by the DUR Board on April 23, 2015. Prior authorization criteria were revised for Xolair® (omalizumab). New prior authorization criteria was established for Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir), Vivitrol® (naltrexone), Xyrem® (sodium oxybate), Vimovo® (naproxen/esomeprazole), and Rayos® (prednisone delayed release). Quantity limitations were revised for Zohydro® (hydrocodone)..

These changes are effective September 1, 2015.

<u>MATERIAL TRANSMITTED</u>	<u>MATERIAL SUPERSEDED</u>
CL CHAPTER 1200 - PRESCRIBED DRUGS	MTL 12/15 CHAPTER 1200 - PRESCRIBED DRUGS

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
Appendix A Section II	Deuxis® (famotidine/ Ibuprofen)	Deleted all criteria for Duexis® (famotidine/ibuprofen) because it has been incorporated into new criteria with Vimovo® in Section C.1.
Appendix A Section P.	Xolair® (Omalizumab)	Updated “Last Reviewed by the DUR Board:” to April 23, 2015. Added words “and failed” in section a., numbers 2, 3, and 4; and section b., numbers 2 and 3.

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
		<p>Added “and” to section a, number 8.</p> <p>Added: “The requested dose is appropriate for the recipient’s pre-treatment serum IgE and body weight.”</p> <p>Added “an allergist/immunologist” to section b., number 4.</p> <p>Under Section 2, Prior Authorization Guidelines, added Table 1: Dosing for Xolair® (omalizumab).</p>
<p>Appendix A Section YY.</p>	<p>Viekira Pak® (dasabuvir- ombitasvir- paritaprevir- ritonavir)</p>	<p>Added new criteria for Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir).</p> <p>Added the Therapeutic Class: Anti-Hepatitis Agent-Polymerase Inhibitor Agent; last reviewed date: April 23, 2015, disclaimer regarding prior authorizations and quantity limits, Coverage and Limitations, and PA Guidelines.</p>
<p>Appendix A Section ZZ.</p>	<p>Vivitrol® (naltrexone)</p>	<p>Added new criteria for Vivitrol® (naltrexone).</p> <p>Added the Therapeutic Class: Opioid Dependence Agent; last reviewed date April 23, 2015; disclaimer regarding prior authorizations; Coverage and Limitations; and PA Guidelines.</p>
<p>Appendix A Section AAA.</p>	<p>Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil)</p>	<p>Added new criteria for Xyrem® (sodium oxybate), Provigil® (modafinil), and Nuvigil® (armodafinil).</p> <p>Also added the Therapeutic Class: non-stimulant Narcolepsy Agents; last reviewed date: April 23, 2015; disclaimer regarding prior authorizations, and quantity limitations; Coverage and Limitations; and PA Guidelines.</p>
<p>Appendix A Section BBB.</p>	<p>Vimovo® (naproxen/ esomeprazole Duexis® (ibuprofen/ famotidine)</p>	<p>Added new criteria for Vimovo®, naproxen/esomeprazole; and Duexis® (ibuprofen/famotidine).</p> <p>Also added the Therapeutic Class: Nonsteroidal.</p> <p>Anti-inflammatory Drug/ Anti-Ulcer Agent Combinations; last reviewed date: April 23, 2015; disclaimer regarding prior authorizations, and quantity limitations; Coverage and Limitations; and</p>

Manual Section	Section Title	Background and Explanation of Policy Changes, Clarifications and Updates
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**Appendix A.
Section CCC.**

**Rayos®
(prednisone
delayed-release)**

PA Guidelines.
Added new criteria for Rayos® (prednisone delayed-release).

Also added the Therapeutic Class: prednisone delayed-release; last reviewed date: April 23, 2015; disclaimer regarding prior authorizations; Coverage and Limitations; and PA Guidelines.

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All drugs in Appendix A may be subject Quantity Limitations.

Check the Nevada Medicaid and Nevada Check Up Pharmacy Manual for a listing of the exact Quantity Limitation.

P. Xolair® (Omalizumab)

Therapeutic Class: Respiratory Monoclonal Antibody Agents

Last Reviewed by the DUR Board: ~~July 24, 2014~~ 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

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:

1. The recipient must be age 12 years or older; and
2. The recipient must have tried **and failed**, or have a contraindication to inhaled oral corticosteroids; and
3. The recipient must have tried **and failed**, or have a contraindication to an oral second generation antihistamine; and
4. The recipient must have 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; and
7. The recipient must have had a pretreatment serum total Immunoglobulin E (IgE) level; and
8. The recipient's current weight must be recorded; **and**
9. **The requested dose is appropriate for the recipient's pre-treatment serum IgE and body weight.**

- b. The recipient has a diagnosis of chronic idiopathic urticaria (CIL), and

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The recipient must meet all of the following criteria:

1. The recipient is age 12 years or older; and
 2. The recipient must have tried **and failed**, or have a contraindication to two oral second generation antihistamines; and
 3. The recipient must have tried **and failed**, or have a contraindication to an oral second generation antihistamine in combination with a leukotriene receptor antagonist; and
 4. The prescriber must be either an **allergist/immunologist**, dermatologist or a rheumatologist.
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				

H. Duexis® (famotidine/ibuprofen)

~~Therapeutic Class: Anti-arthritis~~

~~Last Reviewed by the DUR Board: January 23, 2014~~

~~Duexis® (famotidine/ibuprofen) 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

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

- ~~a. The recipient has an allergy to generic separate famotidine and/or ibuprofen dosage forms; and~~
- ~~b. The recipient has tried and failed a proton pump inhibitor and/or a prostaglandin agent and/or a proton pump inhibitor, in combination with a conventional nonsteroidal anti-inflammatory drug; and~~
- ~~c. The recipient is intolerant of cox-2 inhibitors.~~

2. Prior Authorization Guidelines:

- ~~a. Initial Prior Authorization approval will be for six months.~~
- ~~b. Recertification approval will be for one year.~~
- ~~c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>~~

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III. Daliresp® (roflumilast)

Therapeutic Class: Phosphodiesterase-4 Inhibitors.

Last Reviewed by the DUR Board: July 26, 2012

Daliresp® (roflumilast) 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

Authorization will be given if the following criteria are met and documented:

- a. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting anticholinergic agent;
- b. The recipient has experienced an inadequate response, adverse event or has a contraindication to a long-acting β agonist;
- c. The recipient has experienced an inadequate response, adverse event or has a contraindication to an inhaled corticosteroid;
- d. The recipient has a diagnosis of severe Chronic Obstructive Pulmonary Disease (COPD) associated with chronic bronchitis; and
- e. The recipient has a history of COPD exacerbations.

2. Prior Authorization Guidelines:

- a. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

KKJJ. Hereditary Angioedema Agents

Therapeutic Class: Hereditary Angioedema Agents

Last Reviewed By DUR Board: July 25, 2013

Hereditary angioedema agents 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

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

a. Cinryze® (C1 esterase inhibitor)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and
2. The medication is being prescribed by or in consultation with an allergist or immunologist; and
3. The medication is being used as prophylaxis for hereditary angioedema attacks; and
4. The recipient has experienced an inadequate response or adverse event with an attenuated androgen (e.g. danazol, stanozolol) or antifibrinolytic (e.g. tranexamic acid, aminocaproic acid) agent or has a contraindication to all agents in these classes; and
5. The recipient routinely experiences more than one hereditary angioedema attack per month, or the recipient has a history of laryngeal attacks.

b. Berinert® (C1 esterase inhibitor), Kalbitor® (ecallantide) and Firazyr® (icatibant)

The recipient must meet all of the following:

1. The recipient has a diagnosis of hereditary angioedema; and
2. The medication is being prescribed by or in consultation with an allergist or immunologist; and
3. The medication is being used to treat acute hereditary angioedema attacks.

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2. Prior Authorization Guidelines:

- a. Initial Prior Authorization approval will be for six months.
- b. Prior Authorization requests for continuation therapy will be approved for one year.
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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LLKK. Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide)

Therapeutic Class: Incretin Mimetics

Last Reviewed by the DUR Board: July 26, 2012

Byetta® (exenatide), Bydureon® (exenatide extended-release) and Victoza® (liraglutide) 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

Authorization will be given if the following criteria are met and documented:

- a. The recipient is 18 years of age or older;
- b. The recipient has a diagnosis of type 2 diabetes mellitus; and
- c. The recipient has failed to achieve glycemic control despite an appropriate trial with metformin and/or a sulfonylurea.

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>

MMLL. Kalydeco® (ivacaftor)

Therapeutic Class: Cystic Fibrosis Agent

Last Reviewed by the DUR Board: July 2, 2014

Kalydeco® (ivacaftor) 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

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

- a. The recipient is six years of age or older; and
- b. The recipient has a diagnosis of cystic fibrosis; and
- c. There is documentation that the recipient has had an FDA-approved cystic fibrosis mutation test confirming the presence of one of the following G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N or S549R gene mutationys.

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>

NNMM. Natroba® (spinosad)

Therapeutic Class: Topical Antiparasitics

Last Reviewed by the DUR Board: July 26, 2012

Natroba® (spinosad) is subject to prior authorization.

1. Coverage and Limitations

Authorization will be given if the following criteria are met and documented:

- a. The recipient has experienced an allergy or adverse event with a permethrin or pyrethrin-containing pediculicide product; or
- b. The recipient has experienced a treatment failure with a permethrin or pyrethrin-containing pediculicide product despite a full course of treatment (two applications); or
- c. The recipient has a contraindication to treatment with permethrin or pyrethrin-containing pediculicide product.

2. Prior Authorization Guidelines

- a. Prior authorization approval will be for the date of service only.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

00NN. Platelet Inhibitors

Therapeutic Class: Platelet Inhibitors

Last Reviewed by the DUR Board: January 23, 2014

Brilinta® (ticagrelor) and Effient® (prasugrel) 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

Authorization will be given if the following criteria are met and documented:

a. Brilinta® (ticagrelor)

1. The recipient has a diagnosis of Acute Coronary Syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and
2. The recipient does not have an active pathological bleed or history of intracranial hemorrhage; and
3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and
4. The recipient has been started and stabilized on the requested medication; or
5. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or
6. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.

c. Effient® (prasugrel)

1. The recipient has a diagnosis of ACS (unstable angina, non-ST elevation myocardial infarction or ST elevation myocardial infarction); and
2. The recipient does not have an active pathological bleed or history of transient ischemic attack or cerebral vascular accident (CVA); and
3. The recipient will be receiving concomitant treatment with aspirin in a dose of <100 mg/daily; and

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4. The recipient has a history of percutaneous coronary intervention; and
 5. The recipient has been started and stabilized on the requested medication; or
 6. The recipient has experienced an adverse event with or has an allergy or contraindication to clopidogrel; or
 7. Another clinically appropriate rationale is provided for why clopidogrel cannot be used.
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>

PPOO. Prolia® (Denosumab)

Therapeutic Class: Bone Resorption Inhibitors (Osteoporosis Agents)

Last Reviewed by DUR Board: October 25, 2012

Prolia® (Denosumab) is subject to prior authorization based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

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

a. Postmenopausal Osteoporosis

1. The recipient has a T score \leq -2.5, and
2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture, and
3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently, and
4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.

b. Male Osteoporosis

1. The recipient has a T score \leq -2.5, and
2. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture, and
3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently, and
4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.

c. Non-metastatic Prostate Cancer

1. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture;

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2. The recipient is receiving treatment with androgen-deprivation therapy (e.g., anti-androgen or luteinizing hormone-releasing hormone agents);
 3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
- d. Breast Cancer
1. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture;
 2. The recipient is receiving adjuvant aromatase inhibitor therapy (e.g., anastrozole, exemestane and letrozole);
 3. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
 4. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate; or the recipient has had esophagitis; or the recipient is unable to remain upright.
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>

QQPP. Forteo® (Teriparatide)

Therapeutic Class: Parathyroid/Bone Formation Stimulating Agent (Osteoporosis Agents)
Last Reviewed by DUR Board: October 25, 2012

Forteo® (Teriparatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

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

- a. The recipient has been diagnosed with Postmenopausal Osteoporosis; or Glucocorticoid-Induced Osteoporosis, or the recipient is male and diagnosed with Primary or Hypogonadal Osteoporosis;
- b. The recipient has a T score of ≤ 2.5 ;
- c. The recipient has a history of osteoporotic fracture, or has multiple risk factors for fracture;
- d. The recipient has experienced an inadequate response, adverse event or has a contraindication to one bisphosphonate;
- e. The recipient is not receiving any second line or third line osteoporosis therapy concurrently; and
- f. The total duration of treatment with this agent has not exceeded two years.

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>

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RRQQ. Cesamet® (Nabilone) and Marinol® (Dronabinol)

Therapeutic Class: Antiemetic

Last Reviewed by DUR Board: October 25, 2012

Cesamet® (Nabilone) and Marinol® (Dronabinol) 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

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

a. Cesamet® (Nabilone)

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and
2. The recipient has experienced an inadequate response, adverse event, or has a contraindication to at least one serotonin receptor antagonist; and
3. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and
4. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

b. Marinol® (Dronabinol)

1. The recipient has a diagnosis of chemotherapy-induced nausea and/or vomiting; and
 - a. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one serotonin receptor antagonist; and
 - b. The recipient has experienced an inadequate response, adverse event or has a contraindication to at least one other antiemetic agent; and
 - c. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient; or

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- 2. The recipient has been diagnosed with Acquired Immune Deficiency Syndrome (AIDS) and has anorexia associated with weight loss; and
 - a. The recipient has experienced an inadequate response, adverse event or has a contraindication to megestrol (Megace®); and
 - b. The prescriber is aware of the potential for mental status changes associated with the use of this agent and will closely monitor the recipient.

- 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>

SSRR. Omontys® (Peginesatide)

Therapeutic Class: Erythropoiesis Stimulating Agent (ESA)

Last Reviewed by DUR Board: October 25, 2012

Omontys® (Peginesatide) is subject to prior authorization based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

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

- a. The recipient has a diagnosis of anemia secondary to chronic kidney disease, and
- b. The recipient must be over 18 years of age;
- c. The recipient is receiving dialysis;
- d. Other causes for anemia have been evaluated and ruled out (e.g., iron, vitamin B12 or folate deficiencies);
- e. The recipient's hemoglobin level is <10 g/dL, (laboratory values from the previous 14 days must accompany the request); and
- f. The target hemoglobin level will not exceed 11 g/dL.

2. Prior Authorization Guidelines

- a. Prior Authorization approval will be for one month.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

TTSS. Colony Stimulating Factors (Point of Sale Claims Only)

Therapeutic Class: Colony Stimulating Factors

Last Reviewed by the DUR Board: July 25, 2013

Colony Stimulating Factors 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

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

a. Leukine® (sargramostim)

The recipient must meet one of the following:

1. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or
2. The recipient has a diagnosis of acute myeloid leukemia, and has received induction chemotherapy; or
3. The recipient has a diagnosis of non-Hodgkin's lymphoma, acute lymphoblastic leukemia or Hodgkin's disease and is undergoing autologous bone marrow transplantation; or
4. The recipient is undergoing allogeneic bone marrow transplantation from human leukocyte antigen-matched related donors; or
5. The recipient has undergone allogeneic or autologous bone marrow transplantation and is experiencing engraftment failure or delay.

b. Neulasta® (pegfilgrastim)

The recipient must meet the following criteria:

1. The recipient has a diagnosis of nonmyeloid malignancy and
 - a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of $\geq 20\%$; or
 - b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age >65 , absolute

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neutrophil count (ANC) <100 cells/μL, or the expected duration of neutropenia is > 10 days); or

- c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as secondary prophylaxis.

c. Neupogen® (filgrastim)

The recipient must meet one of the following (1 to 5):

1. The recipient has a diagnosis of nonmyeloid malignancy; and
 - a. The recipient is receiving myelosuppressive anticancer drugs that are associated with a febrile neutropenia risk of $\geq 20\%$; or
 - b. The recipient is at high risk for complications from neutropenia (e.g., sepsis syndrome, current infection, age >65, ANC <100 cells/μL or the expected duration of neutropenia is >10 days); or
 - c. The recipient has experienced a prior episode of febrile neutropenia and the requested drug will be used as a secondary prophylaxis; or
2. The recipient has a diagnosis of acute myeloid leukemia and has received induction or consolidation chemotherapy; or
3. The recipient has a diagnosis of nonmyeloid malignancy and is undergoing myeloablative chemotherapy followed by marrow transplantation; or
4. The recipient has a diagnosis of symptomatic congenital neutropenia, cyclic neutropenia or idiopathic neutropenia; or
5. The requested medication is being used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis.

2. Prior Authorization Guidelines

- a. Prior Authorization approval will be for one month.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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UUTT. Auvi-Q (epinephrine injection device)

Therapeutic Class: Anaphylaxis-Self Injectable Epinephrine

Last Reviewed by the DUR Board: January 23, 2014

Auvi-Q (Epinephrine Injection Device) 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

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

- a. The recipient or recipient's caregiver is unable to read or comprehend written directions.

2. Prior Authorization Guidelines:

- a. Initial Prior Authorization approval will be for one year.
- b. Recertification approval will be for one year.
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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~~VVUU~~.Sovaldi® (sofosbuvir)

Therapeutic Class: Anti-Hepatitis Agents-Polymerase Inhibitor Agents
 Last Review by the DUR Board: January 22, 2015

Sovaldi® (sofosbuvir) 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:

Approval for Sovaldi® (sofosbuvir) for mono-infected or HCV/HIV-1 co-infected recipients will be given if the following criteria are met and documented:

- a. The recipient has a diagnosis of chronic hepatitis C Genotype 1 infection; and the recipient will be treated in combination with peginterferon alfa and ribavirin or, if the recipient is ineligible to receive peginterferon alfa, in combination with ribavirin; or
- b. The recipient has a diagnosis of Chronic Hepatitis C Genotype 2 or 3 Infection; and the recipient will be treated in combination with ribavirin; or
- c. The recipient has a diagnosis of Chronic Hepatitis C Genotype 4 Infection; and the recipient will be treated in combination with peginterferon alfa and ribavirin; or
- d. The recipient has a diagnosis of Chronic Hepatitis C Genotype 1, 2, 3, or 4 infection; and the recipient has a diagnosis of hepatocellular carcinoma and is awaiting a liver transplant; and the recipient will be treated in combination with ribavirin.

2. The initial prescription for Sovaldi must be for a two week supply. Subsequent refills can be up to 34 days.

3. Prior Authorization Guidelines

- a. Prior Authorization approval will be for 12 weeks for ALL of the following:
 1. Recipients with a diagnosis of Chronic Hepatitis C Genotype 1 infection and combination therapy with peginterferon alfa and ribavirin.
 2. Recipients with a diagnosis of Chronic Hepatitis C Genotype 2 infection and combination therapy with ribavirin.
- b. Prior Authorization approval will be for 24 weeks for all of the following:

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1. Recipients with a diagnosis of Chronic Hepatitis C Genotype 1 infection and combination therapy with ribavirin.
 2. Recipient with a diagnosis of Chronic Hepatitis C Genotype 3 infection and combination therapy with ribavirin.
- c. Prior Authorization approval will be for up to 48 weeks or until liver transplantation for recipients with a diagnosis of hepatocellular carcinoma and is awaiting a liver transplant combination therapy with ribavirin.
- d. Prior Authorizations will be renewed in 12 week intervals based on genotype.
- e. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

WWWV.V.Medications for the Treatment of Acne

Therapeutic Class: Acne Agents

Last Reviewed by the DUR Board: July 24, 2014

Acne agents 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

No prior authorization necessary for recipients up to 21 years of age.

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

- a. The recipient is age 21 years of age or older; and
- b. The recipient has a diagnosis of moderate to severe acne (Grade III or higher).

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>

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~~XX~~ WW. Harvoni® (ledipasvir/sofosbuvir)

Therapeutic Class: Anti-Hepatitis Agents-Polymerase Inhibitor Agents
 Last Reviewed by the DUR Board: January 22, 2015

Harvoni® (ledipasvir/sofosbuvir) 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

Approval for Harvoni® (ledipasvir/sofosbuvir) will be given if the following criteria is met and documented:

- a. The recipient has a diagnosis of chronic hepatitis C genotype 1 infection; and
- b. The recipient is 18 years of age or older; and
- c. The requested dose is 90 mg/400 mg, once daily; and

2. The initial prescription for Harvoni® must be for a two week supply. Subsequent refills can be up to 34 days.

3. PA Guidelines

- a. PA approval will be given for eight weeks of therapy if the recipient is treatment-naïve, does not have cirrhosis and as a pretreatment (within the last 12 weeks) HCV RNA viral load less than 6 million IU/mL; or
- b. PA approval will be given for 12 weeks of therapy, if one of the following are met and documented:
 1. The recipient is treatment-naïve, does not have cirrhosis and has a pre-treatment (within the last 12 weeks) HCV RNA viral load greater than or equal to 6 million IU/mL; or
 2. The recipient is treatment-naïve and has cirrhosis; or
 3. The recipient is treatment-experienced (failed treatment with peginterferon alfa + ribavirin ± an HCV protease inhibitor) and does not have cirrhosis. (NOTE: recipients who have failed a previous course of therapy with Sovaldi® is also acceptable to meet this criterion); or
- c. Approval will be given for 24 weeks of therapy if the recipient is treatment-experienced (failed treatment with peginterferon alfa + ribavirin ± an HCV

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protease inhibitor) and has cirrhosis. (NOTE: recipients who have failed a previous course of therapy with Sovaldi® is also acceptable to meet this criterion).

- d. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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YYXX. Xartemis® XR (oxycodone and acetaminophen)

Therapeutic Class: Opioid Analgesic

Last Reviewed by the DUR Board: January 22, 2015

Xartemis® XR (oxycodone and acetaminophen) 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

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

- a. The recipient is 18 years or older; and
- b. A diagnosis code of Acute Pain is documented on the prescription and transmitted on the claim; or
- c. An approved Prior Authorization documenting the recipient meeting the following criteria:
 1. The recipient is 18 years or older; and
 2. A diagnosis code of Acute Pain is documented on the Prior Authorization form.

2. PA Guidelines

- a. More than two fills of a quantity of 60 each, within six months requires an approved Prior Authorization documenting the reason to exceed the prescribing limit.
- b. Prior Authorization approval will be for six months.
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

YY. Viekira Pak® (dasabuvir-ombitasvir-partitavir-paritaprevir-ritonavir)

Therapeutic Class: Anti-Hepatitis Agents-Polymerase Inhibitor Agents
 Last Reviewed by DUR Board: April 23, 2015

Viekira Pak® (dasabuvir-ombitasvir-paritaprevir-ritonavir) is subject to prior authorizations 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

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

- a. The recipient has a diagnosis of hepatitis C virus (HCV) genotype 1; and
- b. The recipient is 18 years of age or older; and
- c. The recipient does not have severe hepatic impairment (Child-Pugh class C); and
- d. The recipient has not failed previous therapy that included an HCV protease inhibitor (i.e. boceprevir (Victrelis®), simeprevir (Olysio®) teleprevir (Incivek®); and
- e. The recipient has not failed previous therapy that included sofosbuvir (Sovaldi®); and
- f. The requested dose is 25/150/100 mg of dasabuvir-paritaprevir-ritonavir (two tablets) once daily in combination with dasabuvir 250 mg (one tablet) twice daily; and
- g. The recipient will be using combination therapy with ribavirin for any of the following:
 1. genotype 1a infection (all)
 2. genotype 1b infection (cirrhosis is present)
 3. recipient has had a liver transplant; and
- h. The requested duration of therapy is appropriate; and
- i. If the recipient has had a liver transplant, they have no or mild hepatic fibrosis (Metavir fibrosis score 2 or less).

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2. Prior Authorization Guidelines

- a. Prior Authorization approvals will be given for a period of 12 weeks at a time.
- b. Total length of therapy authorized will be based on the following:
 - 1. Genotype 1a (no cirrhosis): 12 weeks
 - 2. Genotype 1a (cirrhosis): 24 weeks
 - 3. Genotype 1b: 12 weeks
 - 4. Genotype 1a or 1b (recipient has had a liver transplant): 24 weeks
- c. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

ZZ. Vivitrol® (naltrexone)

Therapeutic Class: Opioid Dependence Agents

Last Reviewed by DUR Board: April 23, 2015

Vivitrol® (naltrexone®) is subject to prior authorizations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

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

- a. The drug is being used for an FDA approved indication; and
- b. Recipients must be given the Naloxone Challenge Test prior to administration to assure recipient is opiate free before initiation of therapy; and
- c. The drug must be delivered directly to the prescriber's office; and
- d. The drug is only to be administered once per month.

2. Prior Authorization Guidelines

- a. Prior Authorization approvals will be for 6 months.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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AAA. Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil)

Therapeutic Class: Narcolepsy Agents (non-stimulants)

Last Reviewed by DUR Board: April 23, 2015

Xyrem® (sodium oxybate), Provigil® (modafinil), Nuvigil® (armodafinil) are subject to prior authorizations 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

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

a. Provigil® (modafinil), and Nuvigil® (armodafinil):

1. The recipient has a diagnosis of narcolepsy.

b. Xyrem® (sodium oxybate):

1. The recipient has tried and failed on Provigil® (modafinil), or Nuvigil® (armodafinil); and/or
2. The recipient has a diagnosis of narcolepsy with cataplexy; and
3. The drug was prescribed by or in consultation with a neurologist or sleep specialist.

2. Prior Authorization Guidelines

a. Prior Authorization approvals will be for one year.

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

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BBB. Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine)

Therapeutic Class: Nonsteroidal Anti-inflammatory Drug/Anti-ulcer Agent Combinations
 Last Reviewed by DUR Board: April 23, 2015

Vimovo® (naproxen/esomeprazole magnesium), Duexis® (ibuprofen/famotidine) are subject to prior authorizations 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

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

- a. The drug is being used for an FDA approved indication; and
- b. The recipient's medical records documents one of the following risk factors for developing a NSAID-related ulcer:
 1. Previous history of a major gastrointestinal bleed, perforation or obstruction; or
 2. Previous history of a peptic ulcer, hemorrhagic gastritis, hemorrhagic gastropathy, or erosive esophagitis; or
 3. Concomitant therapy for an anticoagulant or antiplatelet agent (including aspirin) or chronic oral corticosteroids; or
 4. The recipient has had gastric bypass surgery (Roux-en-Y gastric bypass); and
- c. The recipient is intolerant to a COX-2 inhibitor or has had a gastric or duodenal ulcer while taking a COX-2 inhibitor; and
- d. The recipient has experienced an NSAID-associated ulcer in the past while taking a single-entity proton pump inhibitor (PPI) or prostaglandin agent concomitantly with an NSAID or the recipient is intolerant to both PPIs and prostaglandin agents; and
- e. The recipient's medical records document an inadequate response or adverse reaction with concurrent therapy of an equivalent dose of the individual components.

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2. Prior Authorization Guidelines

- a. Prior Authorization approvals will be for one year.
- b. Prior Authorization forms available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>

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CCC. Rayos® (prednisone delayed-release)

Therapeutic Class: Corticosteroid, Systemic
Last Reviewed by DUR Board: April 23, 2015

Rayos® (prednisone delayed-release) is subject to prior authorizations based on the Application of Standards in Section 1927 of the Social Security Act and/or approved by the DUR Board.

1. Coverage and Limitations

Approval will be given if all of the following criteria are met and documented:

- a. The requested drug is being used for a FDA approved indication; and
- b. The recipient's medical records document an inadequate response or adverse reaction to generic prednisone immediate-release tablets.

2. Prior Authorization Guidelines

- a. Prior Authorization approvals will be:
 1. Initial therapy: 3 months.
 2. Recertification: 1 year.
- b. Prior Authorization forms are available at:
<http://www.medicaid.nv.gov/providers/rx/rxforms.aspx>