Carta Trámite

28 de mayo de 2021

A: Todos los Proveedores Contratados por First Medical Health Plan, Inc. para el Plan Vital, Región Única y Población Vital-X (Virtual)

Re: Carta Normativa 21-0517 relacionada al Informe Requerido sobre Utilización de Opioides en el Plan de Salud del Gobierno

Estimado(a) Proveedor(a):

Reciba un cordial saludo de parte de First Medical Health Plan, Inc. (FMHP).

Adjunto a este comunicado encontrará la Carta Normativa 21-0517 de la Administración de Seguros de Salud de Puerto Rico (ASES).

A través de esta Carta Normativa, la ASES informa que, el pasado 4 de septiembre de 2018, el Plan de Salud del Gobierno adoptó medidas para prevenir y combatir la crisis relacionada a la utilización de opioides entre su población de beneficiarios. El 7 de abril de 2021, se actualizó la "Política para Combatir el Mal Uso de Opioides en el Plan Vital" y se resumieron las guías del Centro para el Control y Prevención de Enfermedades (CDC, por sus siglas en inglés) para el uso de opioides.

Le exhortamos a que lea detenidamente la Carta Normativa 21-0517 y se familiarice con la "Política para Combatir el Mal Uso de Opioides en el Plan Vital".

Si usted tiene alguna pregunta relacionada a este comunicado o necesita información adicional, siéntase en la libertad de comunicarse con nuestro Centro de Servicio al Proveedor al número libre de cargos 1-844-347-7802 de lunes a viernes de 7:00 a.m. a 7:00 p.m. También puede acceder a nuestra página electrónica www.firstmedicalvital.com.

Cordialmente,

Departamento de Cumplimiento
First Medical Health Plan, Inc.

GOBIERNO DE PUERTO RICO
ADMINISTRACIÓN DE SEGUROS DE SALUD
Director Ejecutivo I Jorge E. Galva, JD, MHA I jgalva@asespr.org

Carta Normativa 21-0517

17 de mayo de 2021

A: **Aseguradoras, Compañías de Servicios de Salud Mental, Administrador del Beneficio de Farmacia, Farmacias, Grupos Médicos Primarios y Proveedores Participantes del Plan de Salud del Gobierno**

Asunto: **Informe requerido sobre utilización de Opioides en el Plan de Salud del Gobierno**

Efectivo el 4 de septiembre de 2018, el Plan de Salud de Gobierno adoptó medidas para prevenir y combatir la crisis relacionada a la utilización de opioides entre su población de asegurados. El 7 de abril de 2021 se actualizo la ***"Política para Combatir el Mal Uso de Opioides en el Plan Vital" y*** se resumieron las guías del Centro para el Control y Prevención de Enfermedades (CDC por sus siglas en inglés) para el uso de opioides. Como parte de la reciente revisión a la política, los MCOs deben proveer sus hallazgos a la ASES de los reportes de opioides que reciben mensualmente por parte de MC-RX.

El propósito de esta Carta Normativa es proveer a las compañías aseguradoras las guías para la presentación de este informe de hallazgos, sobre utilización de Opioides entre sus asegurados, y las acciones implementadas para mantenerse en cumplimiento con la política.

Con este propósito, los MCO's debe presentar a la ASES la siguiente información trimestralmente:

1) Persona y Rol responsable en cada MCO de recibir y analizar la data de utilización de opioides provista mensualmente por MC-Rx.
2) Identificar y documentar patrones de sobreutilización por parte de un beneficiario, farmacia o prescriptor.
3) Informe de iniciativas/programas/manejo de casos que llevan a cabo los MCO's para reducir posible sobreutilización de sustancias controladas entre sus beneficiaros.

Las clases de terapia afectadas incluyen sedantes, opioides, medicamentos para diabéticos y medicamentos para la migraña, entre otros. Por ejemplo, a raíz de un reporte de utilización, el MCO puede decidir enviar cartas de intervención a los médicos sobre posibles miembros que estén recibiendo recetas de sustancias controladas de diferentes médicos y/o diferentes farmacias, entre otras posibles acciones. Además, en estos informes, recomendamos que los MCO's documenten lo siguiente:

- Posibles sobre utilizadores de opioides mediante el control de la dosis acumulativa de MME. La información sobre los beneficiarios con MME diario de 90 o más forma parte de los reportes que el MCO actualmente recibe de MC-RX mensualmente.

- Según la política, todos los MCO's deben proveer manejo de casos dirigido a pacientes utilizando más de 90 MME al día.

Los proveedores que tengan preguntas sobre esta normativa deberán contactar a la aseguradora con quien tiene un contrato vigente.

Con la información a ser provista por los MCO's, la ASES podrá evaluar qué programas e iniciativas se están llevando a cabo para reducir la utilización inapropiada, monitoreo de las dosis en los miembros mayores de edad y la detección de terapias duplicadas. La ASES estará enviando invitaciones para reuniones trimestrales con los MCO's en la cual los MCOs deberán realizar una presentación para discutir los hallazgos de estos informes.

Estas medidas adaptadas de las guías del CDC y de CMS persiguen la seguridad de nuestros pacientes. ASES continuará implementando iniciativas como esta que ayuden a combatir la epidemia de opioides y colaborará con las demás agencias locales en esta importante labor.

Agradecemos la cooperación que siempre brindan a la ASES.

Cordialmente,

Jorge E. Galva, JD, MHA
Director Ejecutivo

Planificación

Planning, Quality and Clinical Affairs Office

Government Health Plan (GHP) SALUD VITAL

Policy: Policy to Combat Opioid Misuse in Plan Vital Beneficiaries

Number:	**Effective Date:**	**Number of Pages:** 9
ASES-OPCAC-2021/P001	**April 7, 2021**	

Approved By:

Jorge E. Galva Rodríguez, JD, MHA **Signature:** **Date:04/07/2021**

Executive Director

Reference: "Section 1006 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities or SUPPORT for Patients and Communities Act of 2018 (SUPPORT Act)"

PURPOSE

One of the Puerto Rico Health Insurance Administration (ASES, for its Spanish acronym) main policies is to combat and prevent misuse of prescription opioid drugs under Plan Vital, also known as the Government Health Insurance Plan (GHIP). The policy goal is to ensure safe, appropriate utilization and control of short acting opioids, prevent overutilization and reduce risk of long-term use and diversion.

POLICY

Beginning October 16, 2018, as part of the standard formulary update process, members utilizing short acting opioid medications will be subject to limit changes. Those changes follows Centers for Medicare & Medicaid Services (CMS) recommendations in 2019 Call Letter which are aligned with Centers for Disease Control (CDC) guidelines updated in 2016 and clinically-based prescribing habits on the number of Morphine Milligram Equivalents (MME) a member can receive at any given time. There will be separate limits for members who are new to therapy and members who are existing users of opioids, as outlined below.

Prior Authorization (PA) may be pursued if clinically necessary, the Managed Care Organizations (MCOs) will maintain a standardized procedure for making timely and appropriate coverage determination decisions in accordance with the established criteria as approved by ASES' Pharmacy and Therapeutics (P&T) Committee.

SCOPE

This policy applies to ASES' contracted Pharmacy Benefit Management (PBM) organization, MCOs and their Plan Vital providers including, but not limited to, physicians, hospitals, behavioral facilities, ambulatory facilities, and pharmacies prescribing and/or dispensing outpatient drugs.

BACKGROUND

According to the CDC, the lowest effective dose of short-acting opioids should be prescribed for no more than three (3) days; more than 7 days should rarely be needed (https://www.cdc.gov/drugoverdose/prescribing/guideline.html). Short-acting opioids (i.e. immediate- or regular-release oral morphine, hydromorphone, oxycodone, and codeine) are indicated for short-term relief of moderate to severe pain on an "as needed" basis. These medications are often used in conjunction with a long acting opioid to help relieve breakthrough pain in patients with cancer.

The CDC also recommends use non-opioid treatments first. There is insufficient evidence to support efficacy of long-term opioids and opioids are not first line or routine therapy for chronic pain outside of cancer treatment, palliative care, and end of life care. These substances carry with them the potential for harm from adverse drug events and/or overdose. Opioid drugs also have substantial misuse liability and are often implicated among persons who have developed a substance misuse disorder. Concomitant use of benzodiazepines significantly increases the risk of harm from opioids.

Clinicians must use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day. Higher dosages of opioids are associated with higher risk of overdose and death; evidence shows that limiting or reducing **MME** per day helps avoid harmful effects of opioids and promotes patient safety. Opioid daily doses above **50 MME/day** increase the risk of overdose by at least double.

POLICY DESCRIPTION

While most beneficiaries utilize and clinicians prescribe opioids in ways that are medically appropriate, opioid overutilization is nonetheless a significant concern for the Plan Vital program, and ASES is helping

MCOs and all providers identify individuals potentially at risk for opioid abuse through programs like this to **Combat Opioid Misuse in Plan Vital Beneficiaries.**

A. P&T Opioid Formulary Design Approach

1. Opioids are selected for formulary inclusion based on the recommendations of robust, reliable clinical guidelines, such as:

    i. Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain

    ii. The American Society of Interventional Pain Physicians issued guideline recommendations for the use of opioids in the management of noncancer pain in 2017 (American Society of Interventional Pain Physicians (ASIPP) Guidelines).

    iii. Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-cancer Pain: American Pain Society and The Oregon Pain Treatment Guidelines (https://www.oregonpainguidance.org/pain-treatment-guidelines).

2. In addition to strategic inclusion through consideration of clinical guidelines, retrospective drug utilization review is also used to ensure that the most safe and cost-effective formulations are included in the formularies while ensuring that the patient has formulary alternatives sufficient for the appropriate management of his/her condition.

3. Opioids can be subject to the following Utilization Management (UM) tools:

    i. **Quantity limits (QL)** – these limits can be based on prescribing information data, or if no ceiling dose is established by the manufacturer, the Pharmacy & Therapeutics (P&T) Committee approves the quantity limits.

    ii. Days' Supply Limits - these limits can be based on prescribing information data, formulary or sub formulary where the opioid is included or recommendations from clinical guidelines or CMS. **By law, no refills are allowed for these prescription drugs.**

    iii. Short-acting **(SA)** opioids are covered on the following formularies: Dental, Sub Physical, FEI (emergency), Physical, Ob-gyn and Oncology.

iv. Long Acting **(LA)** Opioids fentanyl (Duragesic) patches and Morphine CR (MS Contin) are covered under Oncology for cancer patients and Physical formulary without quantity limits.

B. Concurrent Drug Utilization Review (cDUR)

1. Supply Limits for Short Acting Opioid Naïve patients

i. Edits will first screen for Cancer diagnosis code and will not initiate prescription limits if one is found.

ii. A 3-7-days' supply limit edit **AND** maximum units per day for opioid-naïve patients will be set up as a hard safety edit.

1. An opioid naïve patient is defined as a patient with no opioid prescription in their most recent sixty (60) days claim history.

2. In most opioids, the adjudication system will allow **ONE (1)** fill within a 30-day timeframe.

iii. When these edits are encountered, pharmacies must adjust the quantity to the limit permitted.

iv. When these edits are encountered, pharmacies and prescribers should follow applicable federal or state dispensing laws for dispensing controlled substances.

v. New supply limits will be implemented for short-acting opioids for opioid naïve patients for the treatment of acute pain.

vi. These limits only affect new opioid users. Members already on a short-acting opioid treatment plan are not impacted.

vii. Beneficiaries have the right to request a coverage determination to allow for extended use (beyond established supply limits) in some situations that must be justified by the prescribing physician.

C. Cumulative Morphine Milligram Equivalent (MME) Doses

1. Opioid-containing drug products are identified within the processing and adjudication system, and the opioid content is determined to allow the processing system to calculate the Morphine Milligram Equivalent (MME) when the pharmacist submits an opioid prescription claim. In other words, the processing and adjudication system screens if the member exceed the soft or hard reject cumulative daily MME limit.

2. Members **NOT** new to therapy (have filled opioids in their most recent 60-day claims history) will be limited to a maximum of 89 morphine-milligram equivalents (MME) per day.

    i. A soft reject is triggered when the cumulative daily MME is between 90 mg MME and 199 mg MME:

        1. As per CMS guidance for CY 2019, this reject can be resolved by the pharmacy using specific reasons codes only after consulting with the prescriber and documenting accordingly.

        2. Pharmacists must document such interventions with physicians for future audits.

    ii. A hard reject is triggered when the cumulative daily MME is equal or over 200 mg MME:

        1. This reject can only be resolved when the pharmacist, prescriber, or beneficiary contacts the plan sponsor to request a coverage determination (PA).

3. This cumulative MME dose is a real-time safety alert at the time of dispensing, which is a proactive step to help ensure that providers and pharmacies are aware that potentially high-risk levels of opioids will be dispensed to their patients and to promote care coordination.

4. This Cumulative Morphine Milligram Equivalent (MME) Edit for Treatment Experienced Opioid Users will not apply to patients with Cancer.

5. This edit is not intended as a mean to implement a prescribing limit or apply additional clinical criteria for the use of opioids but instead to give physicians and pharmacists important additional information about their patients' opioid use, it is not intended to substitute the clinical judgement of the prescribers.

D. Additional Safety Edits

1. Opioid Potentiators - CMS Memorandum Dated March 16, 2018
    i. CNS depressants are often misused or abused in conjunction with opioid analgesics to enhance euphoric effects.

    ii. The FDA cited that the combination of opioids with CNS depressants has resulted in serious side effects, including slowed or difficult breathing, overdoses, and deaths.

    iii. Some of the common CNS depressants may be utilized as opioid potentiators and clinicians should avoid prescribing concurrently with opioids whenever possible:

        1. Benzodiazepines – such as clonazepam and lorazepam are Schedule IV controlled substances with risk of misuse or abuse.

        2. Muscle Relaxants – such as carisoprodol, cyclobenzaprine, baclofen, tizanidine, chlorzoxazone, metholaxone commonly used to treat pain related to spasticity.

        3. Barbiturates including one of the most prescribed Butalbital-Acetaminophen-Caffeine Tab (*Fioricet*)

        4. Sedative Hypnotics (benzodiazepine like hypnotics) – which includes zolpidem are also Schedule IV controlled substances with risk of misuse or abuse.

        5. Gabapentinoids – gabapentin, pregabalin which have multiple indications including the management of pain.

        6. Antihistamines – such as promethazine

7. Antipsychotics as quetiapine have a history of misuse and abuse due to its sedating effects.

2. Duplicate therapy safety edits
    i. Therapeutic Duplications: This safety edit in the pharmacy system looks at the member's current medications and identifies potential duplications to prevent members from taking more than one drug in the same drug class.
        1. The following duplicate therapy safety edits will be effective October 16, 2018:
            a. Opioids indicated for the management of pain (not buprenorphine and buprenorphine/naloxone) - **Hard** Reject to avoid dispensing of two long or short acting opioids at the same time, pharmacies won't be able to use override codes at the point of service.
            b. Benzodiazepines - **Hard** rejects to avoid dispensing two benzos, pharmacies won't be able to use override codes at the point of service.
            c. Sedative Hypnotics - **Hard** Reject to avoid dispensing of two hypnotics at the same time, pharmacies won't be able to use override codes at the point of service.

3. Drug Interactions
    i. Drug-Drug Interactions: Checks the member's current medications and identifies potential instances where a member could be taking two drugs with an identified drug-interaction flag. A drug-drug interaction occurs when two medications taken together could cause an adverse event or affect the intended treatment of one of the medications.
    ii. The following drug interactions edits will be effective October 16, 2018.
        1. A **Soft Reject** will be triggered if the adjudication system finds that the patient is using any of the combinations below. This reject can be resolved by the pharmacist using specific reasons codes if, after using clinical judgment it determined the therapy as appropriate.

a. Opioids and Benzodiazepines
b. Opioids and Sedative Hypnotics
c. Opioids and Barbiturates

2. A **Hard Reject** will be triggered if the adjudication system finds that the patient is using any of the buprenorphine combinations below indicated for the treatment of opioid dependence and will not allow dispensing of opioids to these patients. This reject cannot be resolved by the pharmacist using reasons codes.

    a. Opioid and buprenorphine

    b. Opioid and buprenorphine/naloxone to impede access to an opioid to patients on buprenorphine.

4. Retrospective Opioid Utilization Reports
    i. ASES will follow CMS guidelines for CY 2019 to identify potential opioid overutilizers by monitoring Cumulative MME dose.
        1. Opioid-containing drug products (formulary and non-formulary) within the processing and adjudicating system are identified and the opioid content is determined.
        2. Beneficiaries with daily MME 90 or above will be reported to MCOs on a monthly basis.
        3. All the MCOs must provide appropriate case management aimed at coordinated care to these patients using more than 90MME daily.
        4. MCOs to report on at least a biannual basis results of reports and follow up plans according to policy
        5. ASES will follow CMS guidelines in the review of antipsychotic agents for appropriateness for all children 18 and under including foster children based on approved indications and clinical guidelines

5. Fraud, Waste, and Abuse (FWA) Programs

i. Fraud, Waste and Abuse (FWA) Program is designed to promptly detect and investigate any instances of potential FWA at the pharmacy, prescriber and beneficiary level through utilization patterns involving:

1. Top dispensed drugs;
2. Top pharmacies that have increased dispensing rates;
3. Top prescribers who prescribe most drugs;
4. Top pharmacies that have increased brands dispensing rates;
5. Top pharmacies that have increased controlled substances dispensing;
6. Top members that have increased in drug utilization (including opioids);
7. Identification of any opioids with three or more concurrent benzodiazepines in the same month;
8. Among others.

ii. This program also focuses on the reduction of inappropriate utilization, including minimizing the number of prescriptions filled and quantities per prescription, discontinuing therapies in certain drug classes, reducing dosages in senior members and detecting duplicate therapies. Therapy classes impacted include sedatives, opioids, diabetic medications and supplies, and migraine medications, among others. A component of the utilization management program targets potential abuse of medication (with special focus on controlled substances, such as opioids). Intervention letters to the physicians could, for example, be sent to notify them of possible "doctor or pharmacy shopping", on a case by case basis.

iii. ASES' FWA Program identifies high-risk classified cases by analyzing the billing patterns of its pharmacy network through a series of reports such as those described above. Through this approach, we are able to identify, not only beneficiaries with egregious utilization patterns, but also pharmacies and prescribers.

E. ASES will continue updating this policy to implement additional clinical edit criteria to help ensure safer opioid utilization for Plan Vital beneficiaries.