GOBIERNO DE PUERTO RICO
Administración de Seguros de Salud

Hon. Ricardo A. Rosselló Nevares
Gobernador

Sra. Angela M. Avila Marrero
Directora Ejecutiva

Carta Normativa 18-09-18

18 de septiembre de 2018

A: **Grupos Médicos Primarios y Proveedores Participantes del Plan de Salud del Gobierno**

Asunto: **Estrategias para el manejo de la sobreutilización de Opioides en el Plan de Salud del Gobierno**

Efectivo el 16 de octubre de 2018, el Plan de Salud de Gobierno estará adoptando medidas para prevenir y combatir la crisis relacionada a la mal utilización de los opioides. En la ***"Política para Combatir el Mal Uso de Opioides en MI Salud"*** se resumieron las guías del Centro para el Control y la Prevención de Enfermedades (CDC por sus siglas en inglés) para el uso de opioides. El propósito de esta Carta Normativa es detallar las estrategias específicas, basadas en las guías del CDC, a ser implementadas para contribuir a la contención de esta epidemia.

1. Nuevos límites de prescripción **para los pacientes "Naïve" o considerados nuevos en opioides de corta duración:**

    a. Se implementará un edito de seguridad para limitar la prescripción inicial de opioides para el tratamiento del dolor agudo a no más de **7 días** de suministro.
    b. Las recetas que sean para pacientes "Naïve" y contengan más de **7 días** de suministro rechazarán en el punto de venta (la farmacia).
    c. Los editos no serán aplicados a los pacientes que se identifican con diagnóstico de cáncer.
    d. Paciente "Naïve" a opioides se define como, paciente que no tiene uso de opioides en los pasados 60 días.
    e. Paciente "Naïve" no podrá comenzar su tratamiento con opiodes de larga duración, solo podrán utilizar opiodes de corta duración.
    f. A estos pacientes identificados como "Naïve" en opioides se le aplicarán un máximo de tabletas diarias y el suministro deberá ser de 3 a 7 días (dependiendo del formulario) dentro de un período de 30 días para el tratamiento del dolor agudo, **como explicaremos más adelante en la tabla**.
    g. La farmacia evaluará tanto la cantidad de días, como la cantidad de tabletas diarias y deberá ajustar la cantidad al límite permitido, de acuerdo con el mensaje de alerta que reciba.
    h. Los beneficiarios tendrán el derecho a solicitar una determinación de cubierta, ya sea para tratamiento por más de 7 días o mayor cantidad de tabletas diarias solo en aquellos casos que el médico que prescribe justifique la necesidad de llevar una cantidad mayor a la establecida.
    i. Los formularios de Dental, Sub Físico y Formulario de Emergencia Integrado (FEI, por sus siglas en español) mantendrán las reglas de días de suplido actuales.
    j. Los límites de días de suplido por formulario se detallan a continuación:

Formularios	Días de suplido	Aplicará un máximo de unidades diarias
Dental	**Una** receta de 3 días de suplido en 30 días	X
Sub Físico, FEI	**Una** receta de 5 días de suplido en 30 días	X
Salud Física, Ob-Gyn	**Una** receta de 7 días de suplido en 30 días	X
Oncología	No cambios	

k. Los nuevos límites de cantidad que permitirán despachar un máximo de unidades diarias para los pacientes nuevos se implementarán como se describe a continuación:

Nombre del Opioide de Corta Duración en FMC*	Nombre de Referencia	Formularios	Cantidad Máxima por Día para pacientes Naïve (Nuevos en Opioides de Corta Duración)
Hydromorphone HCl Tab 2 MG	Dilaudid	Salud Física	6 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Hydromorphone HCl Tab 4 MG	Dilaudid	Salud Física	3 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Hydromorphone HCl Tab 8 MG	Dilaudid	Salud Física	1 tableta diaria/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Tab 15 MG	Morphine Sulfate 15	Salud Física	3 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Tab 30 MG	Morphine Sulfate	Salud Física	1 tableta diaria/ 7 días de suplido dentro de un periodo de 30 días
Morphine Sulfate Oral Soln 10 MG/5ML	Morphine Sulfate liq	Salud Física	20 ml diarios/ 7 días de suplido dentro de un periodo de 30 días
Tramadol HCl Tab 50 MG	Ultram	Salud Física	3 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
		Sub-Física, FEI	3 tabletas diarias/5 días de suplido dentro de un periodo de 30 días
Oxycodone w/ Acetaminophen Tab 5-325 MG	Percocet	Salud Física, Ob-Gyn	6 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
Acetaminophen w/ Codeine Tab 300-30 MG	Tylenol with Codeine #3	Salud Física	6 tabletas diarias/ 7 días de suplido dentro de un periodo de 30 días
		Dental	6 tabletas diarias/3 días de suplido dentro de un periodo de 30 días
		Sub-Física, FEI	6 tabletas diarias/5 días de suplido dentro de un periodo de 30 días

Nombre del Opioide de Corta Duración en FMC*	Nombre de Referencia	Formularios	Cantidad Máxima por Día para pacientes Naïve (Nuevos en Opioides de Corta Duración)
Hydrocodone-Acetaminophen Tab 5-325 MG	Norco, Lortab, Lorcet	Salud Física	6 tabletas diarias/7 días de suplido dentro de un periodo de 30 días
		Dental	6 tabletas diarias/3 días de suplido dentro de un periodo de 30 días

*Estos opioides se encuentran también en el formulario de Oncología y los nuevos límites de prescripción no le serán aplicados, se cubrirán todos en suplidos que no excedan 30 días.

2. **Nuevo edito para los pacientes con utilización crónica de opioides de corta y larga duración:**
   a. Se implementará un edito de seguridad para pacientes con utilización crónica utilizando la validación en el sistema de adjudicación del cálculo de Miligramos Equivalentes de Morfina (MME) acumulados por día.
   b. Sistema primero verifica si el paciente tiene historial de uso previo en los pasados sesenta (60) días, de NO tener uso previo, se considera "Naive" y le aplican los límites de prescripción explicados en la sección #1.
   c. Los editos no serán aplicados a los pacientes que se identifican con diagnóstico de cáncer.
   d. De haber uso previo durante este término, el sistema de adjudicación calculará la dosis acumulativa de morfina (MME) por día.
      i. Si la dosis acumulativa, MME/día ≤ 89 la reclamación será aprobada.
      ii. Si la dosis acumulativa, MME/día ≥ 90 hasta 199, sistema detendrá la reclamación y emitirá un mensaje de alerta al farmacéutico de que la reclamación sobrepasa el límite diario de MME permitido para ese opioide.
      iii. El farmacéutico deberá documentar al dorso de la receta la consulta realizada al médico.
   e. Si la dosis acumulativa, MME/día ≥ 200, el sistema detendrá la reclamación y solo será aprobada luego de una determinación de cubierta. El farmacéutico deberá comunicarse con la aseguradora correspondiente para evaluar el caso.

3. **Editos de seguridad adicionales**

   a. **Edito de seguridad para la combinación de potenciadores y opioides.** Los potenciadores son medicamentos que se utilizan para intensificar los efectos del opioide. ASES recomienda precaución en el uso concomitante de opioides y sus potenciadores. Se estará emitiendo un mensaje de alerta en el punto de servicio para que el farmacéutico realice una intervención y evite posibles riesgos a todos los pacientes relacionados a esta combinación de medicamentos.

   b. Los editos de seguridad se aplicarán a los siguientes grupos de potenciadores como se describen a continuación:

Edito de DUR	Clase Terapéutica	Tipo de édito
Terapia Duplicada	Opioides indicados para el dolor (que no sean buprenorphine ni buprenorphine/naloxone indicados para tratamiento de dependencia a opioides)	Sistema rechazará reclamaciones con esta duplicidad

Terapia Duplicada	Benzodiacepinas	"Hard Reject" – no permite códigos de "override"
Interacción de Drogas	Opioide + benzodiacepinas	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioide + Sedativos Hipnóticos	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioide + barbiturates	Sistema emitirá mensaje de alerta al farmacéutico para intervención
Interacción de Drogas	Opioid + buprenorphine, Opioid + buprenorphine/naloxone indicados para tratamiento de dependencia a opioides.	El sistema de adjudicación **no permitirá** el despacho de opioides a pacientes en buprenorfina.

4. Otros cambios, se describen a continuación y aplicarán <u>únicamente</u> a los formularios mencionados:

Nombre del medicamento genérico	Nombre de Referencia	Formulario	Cambio
Butalbital-acetaminofen-cafeina 50-325-40 mg tabs	Fioricet	Salud Física	Nuevo límite de prescripción de 28 tabletas para 7 días de suplido
		Sub Físico, FEI	Nuevo límite de prescripción de 28 tabletas para 5 días de suplido
Meperidine HCl Inj 50 MG/ML	Demerol	Salud Física	Se cubrirá un (1) vial para 30 días de suplido
Meperidine HCl Inj 100 MG/ML	Demerol	Salud Física	Se cubrirá un (1) vial para 30 días de suplido
Morphine Sulfate Oral Soln 100 MG/5ML (20 MG/ML)	Morphine Sulfate (Concentrate)	Salud Física	Se remueve de formulario efectivo inmediatamente.

Exhortamos a los médicos que compartan esta carta con todo el personal que trabaje en su oficina y puedan explicarles los detalles e implicaciones que conlleva. Para información adicional relacionada a este comunicado puede comunicarse puede comunicarse con Triple S- Salud al Libre de Costo 1-800-981-1352 o / Área metro 787-775-1352, TTY/TDD 1-855-295-4040 todos los días de la semana las 24 horas.

Estas medidas adaptadas de las guías del CDC y de CMS serán implementadas para 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,

Angela M. Ávila Marrero
Directora Ejecutiva

Puerto Rico Health Insurance Administration Policy to Combat Opioid Misuse in MI Salud beneficiaries

I. PURPOSE:

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

II. 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. 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.

III. SCOPE

This policy applies to ASES' contracted pharmacy benefit management (PBM) organization, MCOs and their MI Salud providers including, but not limited to, physicians, hospitals, behavioral facilities, ambulatory facilities, and pharmacies prescribing and/or dispensing outpatient drugs.

IV. 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.

V. 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 MI Salud 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 MI Salud 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 Naiive 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 affects 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.

A.H.A.

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 in order 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 commonly 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 <u>can be</u> 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 <u>cannot be</u> resolved by the pharmacist using reasons codes.

A.M.M.

         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 <u>CY 2019</u> to identify potential opioid overutlizers 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.

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 MI Salud beneficiaries.

REVIEWED BY: M. Soto

DATE: 18 / Sept / 2018

APPROVED BY:

DATE: 19 - Sept - 2018