EMPLOYER

Pharmacy Benefit Dimensions®

An Independent Health company

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Clinical programs help monitor efficacy, safety and costs

At Pharmacy Benefit Dimensions, we offer more than administration of our client's prescription drug programs. We also offer assistance in the form of clinical programs to help monitor for drug efficacy, safety and costs.

For example, PBD has a variety of processes in place to help reduce overuse of opioids and inappropriate prescribing practices. As a result of these efforts, overall opioid claims per 1,000 members decreased by 10% from January 2015 to January 2016. We also experienced an additional 8% reduction in 2017.

PBD actively participates in events and drug take back programs (twice a year since 2010) to encourage safe use and disposal of opioid prescription medications. Through these events, PBD works collaboratively with law enforcement, political representatives and other organizations to address the issues surrounding prescription opioid abuse. In addition, PBD and Independent Health have several medical and pharmacy representatives who participate on an Erie County Task Force to address the public health crisis through educational programs and other support mechanisms.

Provider and pharmacy reports are reviewed every six months to identify outliers in prescribing/filling patterns when compared to peers. Questionable providers and/or pharmacies that are identified through these reports and analysis are forwarded to our Special Investigation Unit (SIU) or Quality Management (QM) department for further investigation.

PBD runs ad hoc (monthly/quarterly) reports in response to safety issues such as chronic use of short-acting opioids or concurrent opioid and benzodiazepine use on an as-needed basis. Using these reports, PBD formulates comprehensive communications that incorporates a member's prescription profile to aid prescribers in formulating a safe and effective treatment plan. Additionally, PBD supplies supporting documentation on standards of care and recommendations to avoid adverse outcomes.

Clinical misuse and abuse

Our online pharmacy claim adjudication system is set to message network pharmacists for therapeutic duplications considered significant. Specific therapeutic duplications are set as a hard reject, meaning the pharmacy must call our help desk to verify that the duplication is clinically appropriate. Other duplications are soft rejects, meaning that the claim will reject at the pharmacy, but the pharmacist can override the rejection without the need to call our help desk.

In the case of opioid duplications, the system blocks overlapping supplies of opioid prescriptions at the point of dispensing, whether they are for the same or a different opioid product. Overrides are given when the dispensing pharmacist verifies that the duplication is medically appropriate for the specific patient. The dispensing pharmacist is expected to contact the prescribing physician to determine that the concurrent use of opioids is safe and appropriate. Categories this system applies to are short-acting and long-acting opioids/opiates, acetaminophen-containing products and opioid antagonists.

Drug overutilization and incorrect drug dosage

Our online pharmacy claim adjudication system has edits that are in place to prevent overutilization through quantity limits, opioid duplication limits and blocking early refills.

At the point of dispensing, our system is also set to prevent inappropriate dosing of specified drugs through maximum daily dosage limits or as specified in the formulary. An example would be **maximum acetaminophen dosing**. At the point of dispensing, the pharmacy system blocks prescriptions containing more than 4,000 mg of acetaminophen. Doses greater than this are known to be a risk for hepatotoxicity.

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The PharmaScene

The PharmaScene is designed to keep our clients updated on new drug developments and approvals, as well as other timely drug information. As always, new medications are reviewed for safety, efficacy and cost by our Pharmacy & Therapeutics (P&T) Committee to determine if and/or where they should be placed on our drug formulary.

- Migraine is a disorder characterized by severe headache, generally associated with nausea and/or light and sound sensitivity. It is one of the most common complaints encountered by neurologists in day-to-day practice. Migraine is a common disorder that affects up to 12% of the general population and is more frequent in women than in men. Migraine disorder is most common in those aged 30 to 39 and tends to run in families. In general, there are two types of migraines:
  - Migraine **without aura**: Severe, one-sided throbbing pain, often accompanied by nausea, vomiting, cold hands, sensitivity to sound and light. Nearly 75% of migraines are without aura.
  - Migraine **with aura**: Warning signs develop, which may include visual disturbances or numbness in arm or leg. Warning symptoms subside within 30 minutes followed by severe pain. About 25% of migraines are with aura.

  Patients with frequent or severe migraine headaches who don't respond to acute treatments should receive preventative therapy. Commonly prescribed medications used to prevent migraines include beta blockers, anti-epileptics, Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs), ACE inhibitors, calcium channel blockers, and tricyclic antidepressants.

  A new class of preventative migraine therapy recently hit the market in May 2018 that targets migraine prevention through a new mechanism of action by binding to and inhibiting Calcitonin Gene-related Peptide (CGRP). CGRP transmits pain from vessels within the brain to the central nervous system. Increasing the release of CGRP can trigger a migraine attack in migraine sufferers.

  On May 17, Aimovig® (erenumab) was approved by the FDA for prophylactic treatment of episodic or chronic migraine. This medication is administered by a monthly injection under the skin and does not need to be administered by a health care professional. The price of Aimovig® is listed at $575 per month, totaling about $6,900 per patient per year. Due to the expected utilization of this therapy and the incidence of migraines among the general population, PBD will be closely managing approvals for this therapy for our members. In doing so, we can ensure the maximum number of members achieve appropriate clinical response with the most cost-effective therapies before requiring the use of this medication.

  There are several similar CGRP products being developed by other manufacturers that are expected to hit the market within the next couple of years. Currently, there are two potential approvals by the end of 2018 and one or more potential approvals in 2019. Clinical trials to date have demonstrated similar safety and efficacy among the pipeline candidates.

- The FDA campaign to promote wider use of generics received a bigger media push recently with the addition of radio. Three public service radio announcements, two in English and one in Spanish, feature short messages focused on the fact that generics are safe, effective and money-saving. The campaign began last September with TV and print ads, along with educational brochures and infographics, with a budget of $2 million. The campaign is set to run through March 2019.

  The TV ad, which has run on local and cable channels and in physician offices, features a blue cloud character introduced as "Blue," who's not feeling well and gets a generic prescription from the doctor. Blue wonders if generics "really work as well as name brands?" But the narrator assures Blue that they do, and in the end, Blue saves some green and feels less blue. The agency is hopeful that the ads will reinforce the quality and value of generic drugs.

  "We hope the campaign will complement the agency's other efforts on drug competition. As more generics become available in the marketplace, the FDA wants to continue to let consumers know that approved generic drugs are equal to their brand-name counterparts in safety, effectiveness and quality, often for a lower cost," an FDA spokesperson said.

  PBD's philosophy and formulary management strategies mirror the FDA's message in an effort to leverage the utilization of generic equivalents to promote cost-effective pharmacy utilization for our clients and members.

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If a member is identified as over-using or misusing opioids, PBD has several mechanisms in place to help manage their utilization. These mechanisms include working collaboratively with their prescriber(s) to disseminate prescription filling patterns of concern, implementing a restriction program to one prescriber and one pharmacy, and limits on the dose, quantity and frequency of opioids to be filled.

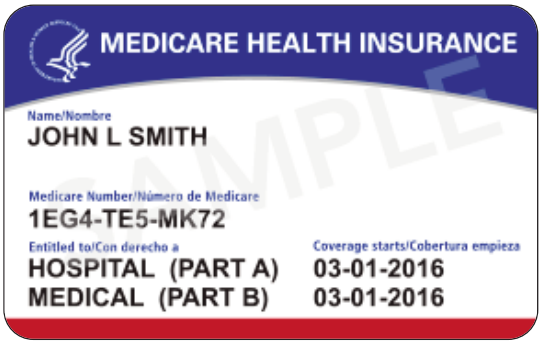
If you have any questions about our Opioid Abuse Prevention program, please contact your account manager.

CMS transitions from Health Insurance Claim number to new Medicare Beneficiary Identifier

The Centers for Medicare and Medicaid Services (CMS) has begun the process of replacing their ID numbers. The Health Insurance Claim number, commonly referred to HIC number or HICN, is a Social Security based number. CMS is replacing the HICN with a new number known as the Medicare Beneficiary Identifier or MBI.

The new MBI will no longer include a beneficiary's SSN, but will instead be an alpha-numeric number. This is the ID number which is printed on the red, white and blue Medicare card used by CMS. This number does not appear on the PBD ID card.

The biggest reason Medicare is removing the HICN is to prevent identity theft. The MBI is confidential, just like a SSN and should be treated as Personally Identifiable Information. Each MBI is unique, randomly generated, and the characters are "non-intelligent," which means they don't have any hidden or special meaning.



MBI FORMAT

An MBI number will have the following format:

- The MBI's 2nd, 5th, 8th and 9th characters will always be a letter
- Characters 1, 4, 7, 10, 11 will always be a number
- The 3rd and 6th characters will be a letter or a number

TIMING

Beginning in April 2018, CMS began issuing new MBI numbers to all new and current Medicare beneficiaries. For current beneficiaries, CMS will be mailing new ID cards in phases. CMS will be allowing a transition period that will allow plans to submit either a member's HICN or MBI number on claims until December 31, 2019. Effective January 1, 2020, all transactions with DOS must be submitted with the MBI number.

WHAT DOES IT MEAN FOR PBD?

While these numbers do not appear on PBD ID cards, they are stored and utilized in PBD's systems as required by CMS for several purposes, including, but not limited to, enrollment and reporting processes. CMS communicated the new MBI numbers to plans so they could update their systems. As of April 1, 2018, plans must now be able to accept a new identifier that replaces the HICN.

WHAT DO THE NEW MEDICARE CARDS MEAN TO MEMBERS WITH MEDICARE?

The MBI won't change Medicare benefits. People with Medicare may start using their new Medicare cards and MBIs as soon as they get them. The effective date of the new cards, like the old cards, is the date each beneficiary was or is eligible for Medicare.

Once beneficiaries get their new Medicare cards with an MBI, they can use their new cards to enroll in a Medicare health (Medicare Advantage) or drug plan. Those Medicare beneficiaries who do choose to enroll in Medicare health and/or drug plans will still also get an identification card from their health and/or drug plans. As always, while beneficiaries are enrolled in health and/or drug plans, they should use the cards from those plans when they get health care and/or prescriptions.

For additional information about the new Medicare cards, visit **www.cms.gov/Medicare/New-Medicare-Card/index.html**.

CAR T-cell therapies promising, but not without concerns

In May, the U.S. Food and Drug Administration (FDA) approved a CAR T-cell therapy called Kymriah® for patients with B-cell lymphoma that have previously tried and failed other therapies. B-cell lymphoma is a type of cancer that affects the body's B-cells, which play an important role in the immune system. Kymriah is a highly specialized and personalized CAR T-cell gene therapy that uses a patient's own altered cells to attack cancer cells. According to The National Cancer Institute, it's estimated there will be 7,000-10,000 potential candidates for Kymriah. This accounts for roughly 0.4-0.6% of all new cancer cases annually. Ultimately, the utilization of this therapy is expected to be low.

While use of this therapy has been successful in treating some cancers, treatments are expensive ($475,000 per treatment) and safety concerns are a continued issue. The most common and life-threating side effect of CAR T-cell therapy is a condition known as cytokine release syndrome (CRS). Commonly referred to as an infusion reaction, CRS is a condition that mimics an immune attack and can result in fever, rash, rapid heartbeat, and trouble breathing. Nearly one third of patients receiving the therapy experience this serious side effect, which requires specific care and medical attention.

At Pharmacy Benefit Dimensions, we actively monitor emerging therapies and medications coming to market. While new gene therapies and medications have promising therapeutic outcomes, our utilization management criteria are stringent, ensuring proper cost management for our clients.

Pharmacy Benefit Dimensions drug formulary update

The Independent Health Pharmacy & Therapeutics (P&T) Committee, which is made up of 15 participating physicians and four network community pharmacists, meets quarterly to review and make changes to the drug formulary. All drug tier decisions made by the committee are based on efficacy and safety first, and economics only after clinical effectiveness has been determined.

Below are changes to the Pharmacy Benefit Dimensions drug formulary that were recommended by the P&T Committee at its March 2018 meeting.

The following medications were added to the formulary:

DRUG	CATEGORY	TIER	COMMENTS
Siklos®	Hematology	Tier 3	PA, SP
Rhopressa®	Glaucoma	Tier 3	ST
Firvanq®	Antibacterial	Tier 3	PA
Biktarvy®	Antiretrovirall	Tier 2	
Symdeko®	Cystic Fibrosis	Tier 2	PA, SP
Erleada®	Oncology	Tier 2	PA, ST

The following changes will be made to the formulary (effective June 1, 2018 unless otherwise stated):

- Aczone® 7.5% – Add ST
- Cuprimine® – Move to NF
- Equetro® – Add PA
- Exjade® – Move to NF
- Pancrease® – Move to T3
- Pertzye® – Move to T3
- Rayos® – Add PA, Remove ST
- Savaysa® – Move to NF
- Viagra® – Move to NF (June 11, 2018)
- armodafinil – Move to T1, remove PA
- cabergoline – Remove PA
- prednisolone ODT – Move to NF
- ribavirin – Remove PA (March 1, 2018)

The following new generic medications are available:

BRAND NAME	GENERIC NAME	CATEGORY
Solodyn®	minocycline	Antibacterial
Namenda XR®	memantine	Alzheimers
Treximet®	naproxen/sumatriptan	Migraine
Locoid®	hydrocortisone butyrate	Dermatology
Syprine®	trientine	Wilson's Disease
Sustiva®	efavirenz	HIV

The following medications were reviewed and will remain non-formulary:

- Eskata®
- Impoyz®
- Lonhala Magnair®
- Segluromet®
- Steglatro®
- Steglujan®
- Xepi®

The following medications were reviewed and will be covered as a medical benefit:

- Giapreza®
- Luxturna® – PA
- Sinuva® – PA

ABBREVIATION KEY
PA: Prior Authorization
ST: Step Therapy
NF: Non-Formulary
SP: Specialty Medication
QL: Quantity Limit
AL: Age Limit