
Just as cold and flu season began, the New York State Department of Health (NYSDOH) issued a new pocket guide to help healthcare providers optimally prescribe antibiotics. These guidelines were released in conjunction with the observance of “U.S. Antibiotics Awareness Week” (November 13 – 19, 2017).

“U.S. Antibiotics Awareness Week” is one aspect of global efforts to raise awareness of the public health threat of antibiotic resistance and the importance of appropriate antibiotic prescribing and use. The Centers for Disease Control and Prevention provides grant funding to NYSDOH for educational outreach on appropriate antibiotic use to healthcare providers and patients. Inappropriate antibiotic prescribing is one of a number of factors that contributes to antibiotic resistance, where bacteria are able to resist the effects of antibiotics intended to kill them.

The new pocket guide goes straight to the essence of clinical treatment guidelines and includes recommendations for both adult and pediatric patients. Adult conditions include acute rhinosinusitis, acute uncomplicated bronchitis, common cold/non-specific upper respiratory tract infection (URI), pharyngitis, and acute uncomplicated cystitis. Pediatric conditions include acute rhinosinusitis, acute otitis media, pharyngitis, URI, bronchiolitis, and urinary tract infections (UTI).

The simple, easy-to-use pocket guide will be available in two versions from four venues:
- As a hard-copy reference card available free from NYSDOH
- As an electronic link that could be integrated into electronic health records
- Download and print as a reference card
- Printed out from the NYSDOH electronic links and posted where providers keep their reference materials.


These guidelines should expedite antibiotic prescribing for the busy healthcare provider by including information to pinpoint when antibiotics may or may not be indicated and to assist providers to select an appropriate antibiotic according to published guidelines.

“US Antibiotic Awareness Week” was previously called “Get Smart Week” and is always observed during the second full week of November.
Andrew M. Cuomo  
Governor  
State of New York

Howard A. Zucker, M.D., J.D.  
Commissioner  
New York State  
Department of Health

Jason A. Helgerson  
Medicaid Director  
Office of Health Insurance Programs  
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On October 19, 2017, the New York State Medicaid Drug Utilization Review (DUR) Board recommended changes to the Medicaid pharmacy prior authorization programs. The Commissioner of Health has reviewed the recommendations of the Board and has approved changes to the Preferred Drug Program (PDP) within the fee-for-service (FFS) pharmacy program. Effective December 14, 2017, prior authorization (PA) requirements will change for some drugs in the following PDP classes:

- Anti-Emetics
- Glucocorticoids - Oral
- Hepatitis C Agents – Direct Acting Antivirals

Also, effective December 14, 2017, the fee-for-service pharmacy program will implement the following parameters recommended by the DUR Board:

**Atopic Dermatitis Clinical Updates**
- Add edits for new product; crisaborole (Eucrisa)
  - Step Therapy – for members 2 years of age or older with a diagnosis of an FDA-approved or compendia-supported indication.
    - Trial with a prescription topical corticosteroid within the three months prior to the prescribing of crisaborole
    - Quantity Limit of 100 grams per 30 days
- Add edits for new product; dupilumab (Dupixent)
  - Step-therapy – for members 18 years of age or older with a diagnosis of an FDA-approved or compendia-supported indication.
    - Trial required with a prescription topical corticosteroid of at least a medium- or high-potency and one other topical prescription agent other than a steroid (within a different class) indicated for Atopic Dermatitis for a combined duration of at least six months prior to the prescribing of dupilumab.
    - Quantity Limit of two cartons (each carton contains two pre-filled syringes) for first 30 days, followed by one carton per 30 days thereafter.

**Rosacea Management**
- Add edits for management of rosacea
  - Diagnosis required for azelaic acid (Finacea), brimonidine (Mirvaso), ivermectin (Soolantra), oxymetazoline (Rhofade), and doxycycline (Oracea)
  - Step therapy – for members with a diagnosis of rosacea
    - Trial with the most cost-effective agent(s) available considering treatment guidelines.

For more detailed information on the DUR Board, please refer to: [http://www.health.ny.gov/health_care/medicaid/program/dur/index.htm](http://www.health.ny.gov/health_care/medicaid/program/dur/index.htm).

For more detailed information on the above DUR Board recommendations, please refer to the meeting summary at: [https://health.ny.gov/health_care/medicaid/program/dur/meetings/2017/10/summary_durb.pdf](https://health.ny.gov/health_care/medicaid/program/dur/meetings/2017/10/summary_durb.pdf).

Please note that PA requirements are not dependent on the date a prescription is written. New prescriptions and refills on existing prescriptions require PA even if the prescription was written before the date the drug was determined to require PA.

The following is a link to the most up-to-date information on the Medicaid FFS Pharmacy Prior Authorization programs. This document contains a full listing of drugs subject to PDP, Clinical Drug Review Program (CDRP),...

To obtain a PA, please call the prior authorization clinical call center at 1-877-309-9493. The clinical call center is available 24 hours per day, 7 days per week with pharmacy technicians and pharmacists who will work with you, or your agent, to quickly obtain a PA.

Medicaid-enrolled prescribers with an active e-PACES account can initiate PA requests through the web-based application PAXpress®. The website for PAXpress® is: [https://paxpress.nypa.hidinc.com/](https://paxpress.nypa.hidinc.com/).

The website may also be accessed through the eMedNY website at [http://www.eMedNY.org](http://www.eMedNY.org), as well as Magellan Medicaid Administration's website at [http://newyork.fhsc.com](http://newyork.fhsc.com).

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**Reminder**

**Authorized Agents for Prior Authorizations of Prescription Drugs**

Health care providers are required to complete the prior authorization (PA) process for various reasons including prescribing a drug for which there is an equally effective lower cost alternative, safety concerns, and/or a potential for inappropriate use. In all cases, prescribers will need to provide their clinical rationale for why the drug should be covered. Only the prescriber or the authorized agent may request a PA. PA requests need to be approved and validated through the Clinical Call Center at 1-877-309-9493.

**Authorized Agent/Third Party Requests:**
- An authorized agent is someone who is an employee of the prescribing practitioner and has access to the patient’s medical records; for example, a nurse, or medical assistant.
- Pharmacists cannot initiate PAs other than for a 72-hour emergency PA.

Prescribers may not contract with or assign authority to dispensing pharmacists to handle his/her PA requests. This would be considered “patient steering.” The patient must be given a choice of where to get their medications or supplies. Federal law prohibits limiting a Medicaid beneficiary’s freedom of choice except under certain circumstances including but not limited to recipient restriction (section 1902(a)(23) of the Social Security Act). Complaints from providers and enrollees involving steering should be sent to the Office of the Medicaid Inspector General (OMIG). The OMIG website contains online forms for complaints and can be accessed at: [https://www.omig.ny.gov/index.php/fraud/file-an-allegation](https://www.omig.ny.gov/index.php/fraud/file-an-allegation).

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New York State Medicaid Reimbursement for Pasteurized Donor Human Milk

The July 2017 Medicaid Update advised providers that in accordance with the 2017-2018 state budget, pasteurized donor human milk (PDHM) is a covered Medicaid benefit for inpatient use. New York State (NYS) Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) will begin reimbursing for PDHM, outside of the inpatient bundled payment, effective December 1, 2017 for FFS and February 15, 2018 for the MMC plans.

PDHM is covered for infants who:

- Have a documented birth weight of less than 1500 grams (3.3 pounds); or
- Have a congenital or acquired condition that places the infant at a high risk of developing necrotizing enterocolitis (NEC) and/or infection.

Coverage of PDHM is for infants who meet the criteria outlined above and one or more of the following conditions:

- Are medically or physically unable to receive maternal breast milk or participate in breast feeding; or
- Are unable to participate in breast feeding despite optimal lactation support; or
- Are born to mothers whose breast milk isn’t suitable for consumption due to the presence of certain substances or disease; or
- In cases where the mother is medically or physically unable to produce maternal breast milk at all or in sufficient quantities.

This article provides information on how to bill Medicaid for the inpatient use of PDHM. NYS tissue banking regulations require that PDHM be distributed only by tissue banks licensed by the NYS Department of Health and only with a written medical order. Of note, in order to provide medically fragile infants PDHM, a hospital must first have a tissue bank license from the NYS Department of Health that includes human milk. Information on how to obtain such license is available at: https://www.wadsworth.org/regulatory/tissue-resources.

Fee-for-service (FFS) Billing

Hospitals who are appropriately licensed to give PDHM will be reimbursed outside the All Patients Refined Diagnosis Related Groups (APR-DRG). Hospitals should bill PDHM per actual acquisition cost for the quantity of milliliters (mL) delivered to the patient per day using Healthcare Common Procedure Coding System (HCPCS) code T2101 "Human breast milk processing, storage and distribution only." Hospitals should only bill for the amount dispensed, rounding up to the nearest mL (1mL = 1 unit for billing purposes).

Note, although T2101 is listed on the ordered ambulatory fee schedule, coverage is for inpatient use only (and not for outpatient use). Only inpatient providers can bill T2101.

Reminder: Fortifiers continue to be reimbursed within the APR-DRG payment to the facility and cannot be billed outside of the APR/DRG payment.

Medicaid FFS policy questions may be directed to the Office of Health Insurance Programs’ Division of Program Development and Management at (518) 473-2160. Questions regarding Medicaid FFS billing or claims should be directed to the eMedNY Call Center at 1-800-343-9000.

Medicaid Managed Care (MMC) Plan Billing

MMC Plans will also be providing reimbursement for PDHM outside of the hospital’s bundled inpatient payment. Hospitals who are licensed to provide PDHM will be required to bill plans using HCPCS code T2101 so that provision can be monitored. Hospitals participating in MMC should check with the individual health plans to determine how each MMC plan will implement this policy. Questions regarding MMC reimbursement and/or documentation requirements should be directed to the enrollee’s MMC plan.
New York State Medicaid Will Begin Covering Tisagenlecleucel

New York State (NYS) Medicaid fee-for-service (FFS) and Medicaid Managed Care (MMC) will begin covering tisagenlecleucel (brand name KYMRIAH™) for members who have a diagnosis of acute lymphoblastic leukemia (ALL) when the member meets the criteria outlined in this policy. This coverage policy is effective December 1, 2017 for FFS and February 15, 2018 for MMC.

Tisagenlecleucel is a chimeric antigen receptor T cell (CAR-T) therapy for the treatment of patients twenty-five years of age or younger with B-cell precursor ALL that is refractory or in second or later relapse. Tisagenlecleucel is a one-time treatment that uses a patient’s own T cells to fight cancer. Tisagenlecleucel is the first therapy based on gene transfer that has been approved by the FDA.

**Coverage Policy:**
In accordance with FDA indications, Medicaid reimburses for tisagenlecleucel when the following criteria are met:

- The patient must have a diagnosis of B-cell precursor ALL;
- The patient must be 25 years of age (up to the end of the 25th year) or younger; and
- The ALL must be refractory or in second or later relapse.


**Medicaid Managed Care:**
- Providers participating in MMC should check with the individual health plans to determine how each MMC plan will apply this policy.

**Fee-For-Service Billing:**
- Hospitals that are appropriately certified to administer tisagenlecleucel will be reimbursed for tisagenlecleucel using the ordered ambulatory fee schedule. Payment for tisagenlecleucel will be made in addition to the inpatient APR-DRG payment or, if administered on an outpatient basis, in addition to the outpatient APG payment.
- Hospitals are to submit a separate ordered ambulatory claim for tisagenlecleucel. The ordered ambulatory claim should be submitted on paper (using the eMedNY 150003 claim form) and should include the hospital’s actual acquisition cost by invoice. Documentation of medical necessity that includes the criteria listed above must accompany the claim. Ordered ambulatory billing guidelines can be found at: [https://www.emedny.org/ProviderManuals/OrderedAmbulatory/PDFS/OrderedAmbulatory_Billing_Guidelines.pdf](https://www.emedny.org/ProviderManuals/OrderedAmbulatory/PDFS/OrderedAmbulatory_Billing_Guidelines.pdf).
- Providers are reminded that any off-invoice discounts or rebates received from the manufacturer should be passed back to Medicaid. Additionally, consistent with any performance guarantee conveyed by the manufacturer of KYMRIAH™ (e.g. providers will only pay if the patient goes into remission), Medicaid should not be billed if no payment has been made to the drug manufacturer.
- From December 1, 2017 through December 31, 2017, HCPCS code J3590 (unlisted biologic) should be used to bill for tisagenlecleucel. The associated National Drug Code (NDC) must be included on the claim.
- Effective January 1, 2018, hospitals should bill using HCPCS code Q2040 (tisagenlecleucel, up to 250 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per infusion). The associated NDC must be included on the claim.
- Storage and handling charges are included in the APR-DRG inpatient payment and the APG outpatient payment and will not be reimbursed separately.
Questions:

- Questions regarding Medicaid FFS billing, please contact eMedNY Provider Services at (800) 343-9000.
- Policy questions regarding Medicaid FFS may be directed to the Office of Health Insurance Programs (OHIP), Division of Program Development and Management at (518) 473-2160.
- Questions regarding MMC reimbursement and/or documentation requirements should be directed to the enrollee’s MMC plan.

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Compliance Certification Reminder:
Federal Deficit Reduction Act of 2005

The New York State Office of the Medicaid Inspector General (OMIG) is reminding all providers subject to the compliance certification requirements under Title 42 of the United States Code Section 1396a(a)(68), [42 USC §1396a(a)(68)] that Federal Deficit Reduction Act (DRA) certification begins December 1 for the federal fiscal year ending September 30, 2017.

The DRA Certification Form and Frequently Asked Questions pertaining to the DRA certification obligation are available on OMIG’s website at: https://omig.ny.gov/dra-certification. A webinar detailing compliance certification obligations can be found at: https://omig.ny.gov/information/webinars.

As a reminder, 42 USC §1396a provides in relevant part that:

(a) A State plan for medical assistance must—
   (68) provide that any entity that receives or makes annual payments under the State plan of at least $5,000,000, as a condition of receiving such payments, shall—
      (A) establish written policies for all employees of the entity (including management), and of any contractor or agent of the entity, that provide detailed information about the False Claims Act established under sections 3729 through 3733 of title 31, United States Code, administrative remedies for false claims and statements established under chapter 38 of title 31, United States Code, any State laws pertaining to civil or criminal penalties for false claims and statements, and whistleblower protections under such laws, with respect to the role of such laws in preventing and detecting fraud, waste, and abuse in Federal health care programs (as defined in section 1320a-7b(f) of this title);
      (B) include as part of such written policies, detailed provisions regarding the entity’s policies and procedures for detecting and preventing fraud, waste, and abuse; and
      (C) include in any employee handbook for the entity, a specific discussion of the laws described in subparagraph (A), the rights of employees to be protected as whistleblowers, and the entity’s policies and procedures for detecting and preventing fraud, waste, and abuse; ...

OMIG monitors a provider’s certification status and conducts reviews of the materials required by 42 USC §1396a(a)(68). For questions about the DRA certification obligation or the DRA Certification Form, providers can contact OMIG’s Bureau of Compliance at (518) 408-0401 or by email at: compliance@omig.ny.gov.

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Self-Disclosure of Medicaid Overpayments

The Office of the Medicaid Inspector General (OMIG) has updated the information on its website regarding the self-disclosure of Medicaid overpayments to better assist providers with the reporting of Medicaid overpayments.

Updates include:

• A comprehensive overview of what a self-disclosure is, and the statutes and regulations that require the reporting of Medicaid overpayments;
• A new, convenient, easy-to-complete self-disclosure form;
• Easy-to-follow self-disclosure submission information and secure file transfer instructions; and
• A submission checklist with Frequently Asked Questions.

To view these updates or learn more about how to self-disclose a Medicaid overpayment, visit the site at: https://omig.ny.gov/self-disclosure. To answer any questions or for more information about the reporting of Medicaid overpayments, contact OMIG’s Self-Disclosure Unit by phone at 518-402-7030, or by email at: selfdisclosures@omig.ny.gov.

NY Medicaid EHR Incentive Program Update

The NY Medicaid Electronic Health Records (EHR) Incentive Program provides financial incentives to eligible professionals and hospitals to promote the transition to EHRs. Providers who practice using EHRs are in the forefront of improving quality, reducing costs, and addressing health disparities. Since December 2011, more than $870 million in incentive funds have been distributed through 30,191 payments to New York State Medicaid providers.

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<td>Payments Made: 30,191</td>
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2017 Public Health Registration Deadline - December 1

All providers who participate in the NY Medicaid EHR Incentive Program must meet the Public Health Reporting objective. To do so, providers must register their intent to submit data to Public Health before or within 60 days of the start of their EHR Reporting Period.

The final 90-day reporting period available in 2017 is October 3, 2017 - December 31, 2017. Friday, December 1, 2017 is the last day that a provider can submit a Registration of Intent for this period.

Registration of Intent is submitted via the Meaningful Use Registration for Public Health (MURPH) System, which is hosted on the NYS Health Commerce System (HCS). Only one registration is required. If you have previously registered, you may "edit" the existing registration with any changes; a new registration should NOT be submitted.

Contact us at 877-646-5410, option 2 or hit@health.ny.gov. Questions? We have a dedicated support team ready to assist.
Office of the Medicaid Inspector General:
For suspected fraud or abuse complaints/allegations, call 1-877-87FRAUD, (877) 873-7283, or visit
www.omig.ny.gov.

Provider Manuals/Companion Guides, Enrollment Information/Forms/Training Schedules:
Please visit the eMedNY website at www.emedny.org.

Providers wishing to listen to the current week's check/EFT amounts:
Please call (866) 307-5549 (available Thursday PM for one week for the current week's amount).

Do you have questions about billing and performing MEVS transactions?
Please call the eMedNY Call Center at (800) 343-9000.

Provider Training:
To sign up for a provider seminar in your area, please enroll online at
http://www.emedny.org/training/index.aspx. For individual training requests, call (800) 343-9000.

Beneficiary Eligibility:
Call the Touchtone Telephone Verification System at (800) 997-1111.

Medicaid Prescriber Education Program:
For current information on best practices in pharmacotherapy, please visit the following websites:
http://www.health.ny.gov/health_care/medicaid/program/prescriber_education/presc-educationprog
http://nypep.nysdoh.suny.edu/home

Need to change your address? Does your enrollment file need to be updated because you have experienced a change in ownership? Do you want to enroll another NPI? Did you receive a letter advising you to revalidate your enrollment?
Visit https://www.emedny.org/info/ProviderEnrollment/index.aspx and choose the link appropriate for you (e.g., physician, nursing home, dental group, etc.).

Medicaid Electronic Health Record (EHR) Incentive Program questions?
Contact the New York Medicaid EHR Call Center at (877) 646-5410 for assistance.

Comments and Suggestions Regarding This Publication?
Please contact the editor, Chelsea Cox, at medicaidupdate@health.ny.gov.