Collaborative Drug Therapy Management in Ambulatory Oncology

Speakers

Lilia Davenport

PharmD, BCPS, BCOP

Clinical Pharmacy Manager and Oncology Pharmacotherapy Specialist

The Brooklyn Cancer Center

The Brooklyn Hospital Center

Samantha Paone

PharmD, MBA, BCPS

Ambulatory Hematology/Oncology Clinical Pharmacy Specialist

Staten Island University Hospital

Northwell Health

NYSCHP New York State Council of Health-sy Pharmacists

Objectives

- Provide an overview of the Collaborative Drug Therapy Management (CDTM) program in ambulatory oncology
- Identify the credentialing path required of a CDTM ambulatory oncology pharmacist in NYS
- Detail the role of a CDTM pharmacist in ambulatory oncology
- Discuss legislative issues that impact CDTM pharmacists and oncology patients
- Assess the impact of a CDTM pharmacist in ambulatory oncology

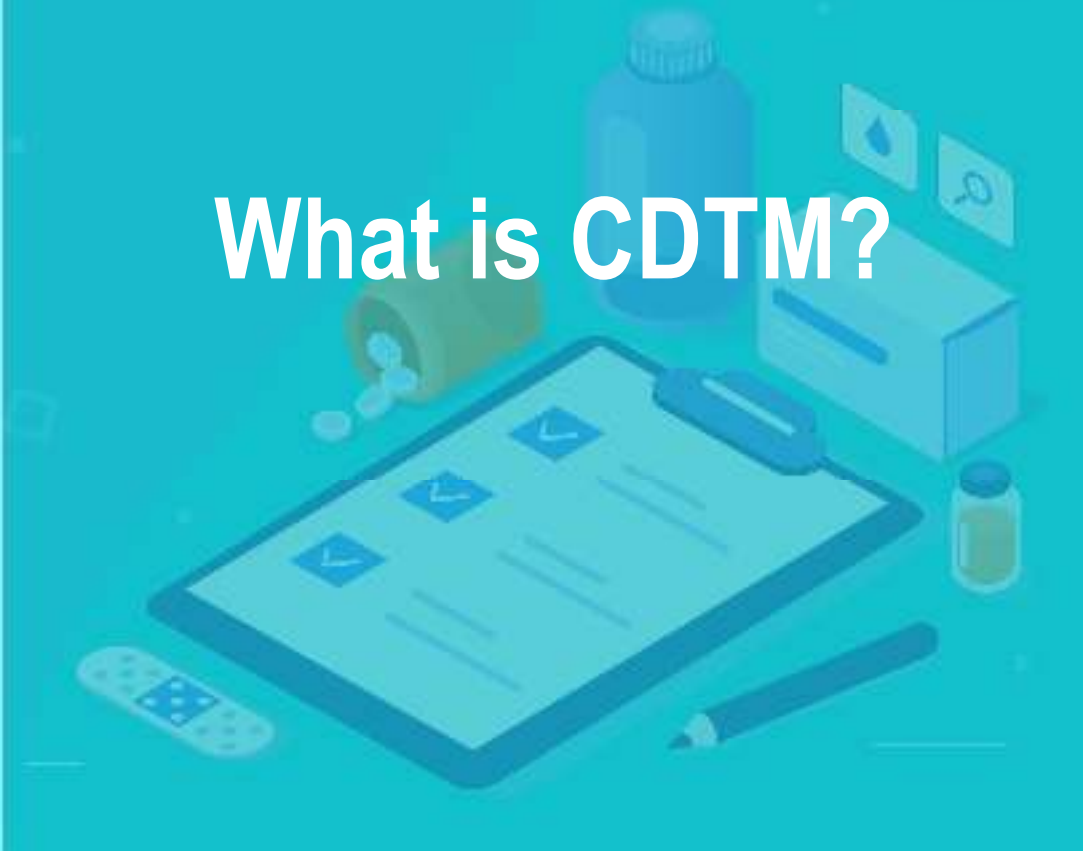
NYSCHP | New York State Council of Health-system Pharmacists

Disclosures

- The authors of this presentation have no relevant financial or non-financial relationships to disclose

NYSCHP | New York State Council of Health-system Pharmacists

What is CDTM?

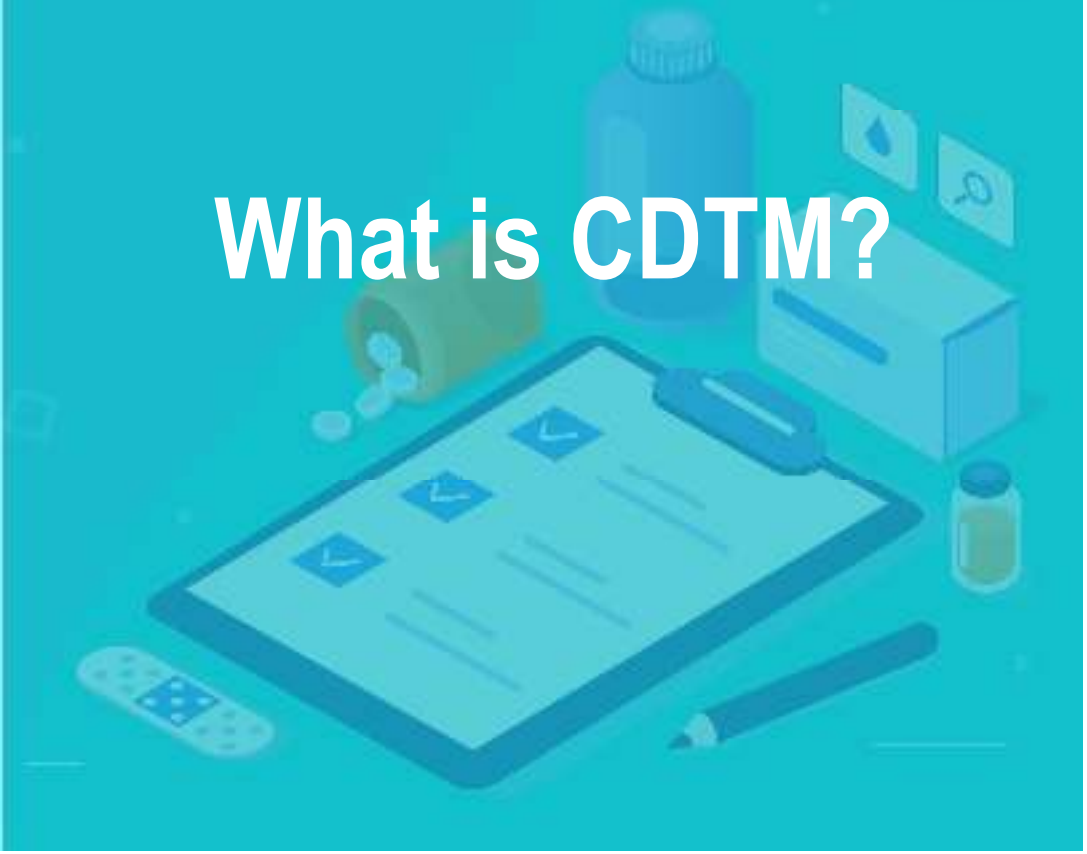


- **CDTM is a formal partnership between a pharmacist and physician or group of pharmacists and physicians to allow the pharmacist to manage a patient's drug therapy**

- Under CDTM agreement with a physician, a clinical pharmacist is allowed to manage chronic conditions such as DM, HTN, HLD, HF, asthma (order labs, adjust doses, monitor responses to therapy, etc)
- Started as a demonstration project in 2011
- Only qualified pharmacists can practice CDTM

NYSCHP | New York State Council of Health-system Pharmacists

What is CDTM?



- **CDTM in Ambulatory Oncology**
  - **Protocol between Oncologist and Pharmacist**
  - **Allows drug therapy management**
    - Specified oncology disease states
    - Specified lab and diagnostic study orders
    - Medication therapy optimization
      - Initiation, monitoring, modifying medications
  - **Medication counseling session**
  - **Medication reconciliation**
  - **Screening for financial toxicity**
  - **Screening for patient adherence**
  - **Adverse effect management**
  - **Referral to other specialists if necessary**

NYSCHP | New York State Council of Health-system Pharmacists

Example of CDTM Protocol in Ambulatory Oncology

[Title]

Example: Hematology/Oncology Department and Department of Pharmacy
HEMATOLOGY/ONCOLOGY PHARMACOTHERAPY CLINIC

[Background]

Clinical oncology pharmacists play an important role in ambulatory care by functioning as oncologist extenders. There are several settings in which a clinical pharmacist can practice to optimize patient health outcomes through programs such as Medication Therapy management (MTM) and Collaborative Drug Therapy Management (CDTM). The concept of MTM was designed to improve collaboration among pharmacists and other healthcare professionals, enhance communication between patients and their healthcare team, and to optimize medication use to improve patient outcomes.[1] The total cost of looking after patients with medication-associated errors exceeds $40 billion each year. [3] CDTM is a formal partnership between pharmacists and physicians which allows the pharmacist to manage a patient's drug therapy. CDTM allows pharmacists to initiate or adjust patient medications, order immunizations, obtain laboratory tests, manage drug toxicities, improve adherence, resolve medication access issues, and give referrals to specialists. The benefits of pharmacists providing these roles have been shown in several studies.[4-7]

Provide background on MTM and CDTM including cost savings

[Rationale]

Instituting a Hematology/Oncology Pharmacotherapy Clinic will improve patient outcomes, reduce readmission rates and decrease care costs by enhancing the following aspects of medication therapy management:

I. Medication Reconciliation
II. Drug Utilization Review
III. Therapeutic Drug Monitoring
IV. Improving patient understanding of medications and disease states

Include rationale for providing CDTM services with references

[Protocol]

I. Hematology/Oncology Pharmacotherapy Clinic consists of collaborative team of physicians and pharmacotherapy specialists, including pharmacy residents.
II. Patients who follow up by a Hematology/oncology physician may be referred to the Hematology/oncology Pharmacotherapy Clinic for all new oral oncolytics starts and/or anticoagulation therapy.
III. Pharmacotherapy specialists will follow national guidelines and evidence-based medicine for medication therapy management of Hematology/Oncology disease states and supportive care, including but not limited to: breast cancer, prostate cancer, lung cancer, skin cancer, colon Cancer, bladder cancer.
IV. The following patient-specific parameters will be assessed by pharmacotherapy specialist: demographics, history of present illness, medication and allergy history, medication access, pertinent vitals, labs and diagnostic studies (including CBC, CMP, hepatic panel, hepatitis B panel, TFT, lipid panel, PT/INR, urinalysis), adverse effects from chemotherapy, immunotherapy, or target therapy.
V. Medication adjustment and prescriptions may be prescribed by the pharmacotherapy specialist and will be communicated to the attending physician via EMR.
VI. Patient education will be provided to the patient and updated in the EMR
VII. A pharmacotherapy clinic note will be documented in the EMR with each visit and will be shared with the collaborating physician.
VIII. Pharmacotherapy specialists will provide referral to other speciatis as deemed necessary
IX. Pharmacotherapy specialists involved and participating in the pharmacotherapy clinic will be credentialed in CDTM as per standards set by NYS Board of Pharmacy.

List conditions such as obtaining referrals, managing specific disease states, ordering labs, prescribing authority, documentation

[Quality Assurance]

I. Attending physicians of Hematology/Oncology clinic will be the collaborating physicians for the Hematology/Oncology Pharmacotherapy Clinic and will be available for consultation
II. Periodic analysis of outcomes will be conducted to further maximize the above protocol
III. Interventional activities records are kept to monitor and prospectively review the impact of the Hematology/Oncology Pharmacotherapy Clinic.

Analysis of outcomes

[Reference]

1. Medication therapy management in pharmacy practice: core elements of an MTM service model (version 2,0). J Am Pharm Assoc (2003). 2008;48(3):341-53.
2. Centers for Medicare and Medicaid. (2020), Medication Therapy Management | CMS.
3. Tarig RA, Vashisht R, Sinha A, Scherbak Y. Medication Dispensing Errors And Prevention.
4. Randolph LA, Walker CK, Nguyen AT, Zachariah SR. Impact of pharmacist interventions on cost avoidance in an ambulatory cancer center. J Oncol Pharm Pract. 2018 Jan;24(1):3-8
5. Ellis SL, Carter BL, Malone DC, et al. Clinical and economic impact of ambulatory care clinical pharmacists in management of dyslipidemia in older adults; the IMPROVE study. Impact of Managed Pharmaceutical Care on Resource Utilization and Outcomes in Veterans Affairs Medical Centers. Pharmacotherapy. 2000;20(12): 1508-16.
6. Hirsch JD, Steers N, Adler DS, et al. Primary care-based, pharmacist-physician collaborative medication-therapy management of hypertension: a randomized, pragmatic trial. Clin Ther. 2014;36(9):1244-54.
7. Wright AL, Matta SF, Kert JR. Expansion of pharmacist practice in oral oncolytic therapy with a collaborative practice agreement. J Oncol Pharm Pract. 2020 Dec;26(8):1886-1893.

[Signatures]

NYSCHP | New York State Council of Health-system Pharmacists

Patient Consent

- Patient or his/her authorized representative must sign consent to participate in CDTM services and agree to comply with therapeutic plan
- Previously, consent to the CDTM must be in writing
- May be made with use of an electronic signature
- Consent must be noted on patient's chart
- If electronic signature is used, consent cannot be incorporated in general patient consent

Patient Consent Form

NORTHWELL HEALTH

CDTM PATIENT CONSENT FORM

New York State allows for qualified pharmacists to manage clients' medication regimens independently or in collaboration with a supervising physician. To this practice, a Doctor of Pharmacy and/or Pharmacist, meeting all necessary qualifications, will have the privilege to manage your medications and specific health conditions as an authorized practitioner, under a Collaborative Drug Therapy Management (CDTM) Collaborative Practice Agreement with an overseeing healthcare provider.

Patient Consent:

I have been told that pharmacist will be working with my doctor to improve my medical results as a result of optimizing the management of my health conditions. I understand that these pharmacists have undergone specific training and have advanced knowledge in managing patients' medications and disease states. I also understand that by consenting to have the pharmacist provide this medication management, they will be regularly communicating with the overseeing collaborating provider. Additionally, I understand that by agreeing to participate, my primary care provider and other healthcare providers may be notified. As part of this medication management program, in order for my care provider, the pharmacists may need to obtain my complete medical history, may provide education or teaching, may perform assessments, may order certain tests and may adjust my medication regimen to provide the most appropriate medication therapy to treat my conditions.

I give my permission to the pharmacists to perform these activities. I understand that this service is intended to complement not replace the services provided by my physician. I understand that I am not in any way obligated to have my medications managed by a pharmacist through the clinic and if I withdraw my consent they will no longer provide medication management services. I understand that I have the right to withdraw consent at any time and that withdrawal or consent will be documented in my medical record. I understand that withdrawing my consent in this program will not prevent me from obtaining my medical care and treatment from my healthcare provider.

Patient or authorized representative (print):

Patient or authorized representative signature: Date/Time:

Witness (print):

Witness signature: Date/Time:

University of the State of New York – New York State Education Department. Collaborative Drug Therapy Management Use of Electronic Signature. Nysed.gov.

NYSCHP | New York State Council of Health-system Pharmacists

Poll Question

What challenges did you encounter before implementing/while performing CDTM services? (Select all that apply)

NYSCHP New York State Council of Health-system Pharmacists

Developing a Practice Agreement

- Must develop a relationship with your provider(s)
- Trust develops over time
- Begin with several routine interactions with the providers
- Address common concerns including pharmacist's level of training and experience in delivering patient care services
- Offer a basic service (refill authorizations) with intent to demonstrate success, and work collaboratively before an agreement is made
- Be prepared to discuss specific goals and benefits of collaboration and how the collaboration can enhance patient care and metrics

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Pharmacist Credentialing in NYS

- Approval is needed from the New York State Education Department (SED)
  - Submit form with required supporting documentation prior to entering into CDTM practice
  - https://www.op.nysed.gov/professions/pharmacist/collaborative-drug-therapy-management
- Pharmacists must:
  - Be employed or affiliated with an eligible facility
  - Currently licensed and registered in NY
  - Meet the education and experience requirements
- CDTM protocols are not required to be sent to SED

University of the State of New York – New York State Education Department. Collaborative Drug Therapy Management (CDTM). Nysed.gov.

NYSCHP New York State Council of Health-system Pharmacists

CDTM Pharmacist Requirements

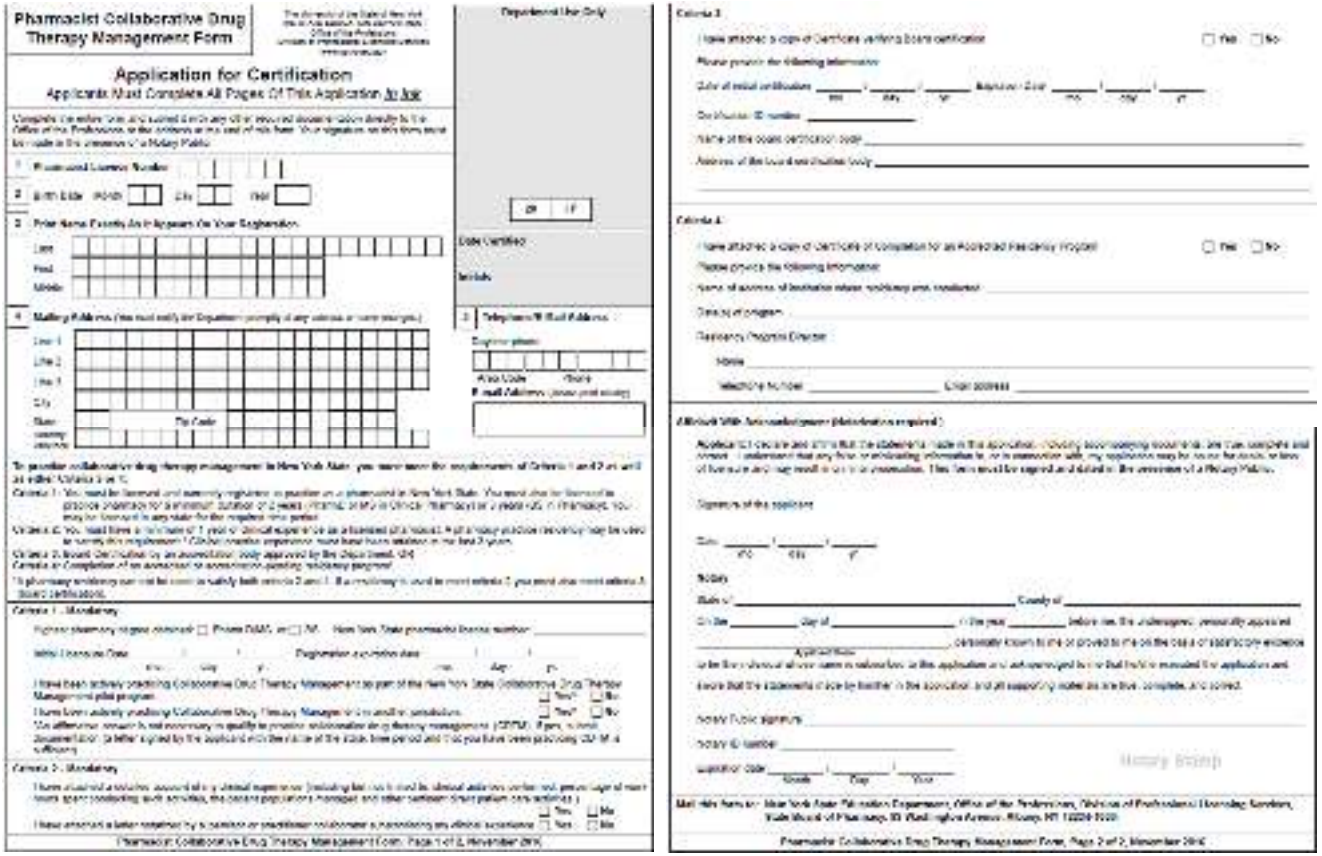
Terminal Degree: PharmD or MS in Clinical Pharmacy	Criteria 1	Number of Years of Licensure ≥ 2	Must meet BOTH Criteria 1 and 2 to qualify
	Criteria 2	Clinical Experience ≥ 1 year	
	In addition, one of the following must be met*:		
	Criteria 3	Board Certified	If no, must meet Criteria 4
	Criteria 4	Completion of Residency Program	If no, must meet Criteria 3

Terminal Degree: BS in Pharmacy	Criteria 1	Number of Years of Licensure ≥ 3	Must meet BOTH Criteria 1 and 2 to qualify
	Criteria 2	Clinical Experience ≥ year	
	In addition, one of the following must be met*:		
	Criteria 3	Board Certified	If no, must meet Criteria 4
	Criteria 4	Completion of Residency Program	If no, must meet Criteria 3

NYSCHP New York State Council of Health-system Pharmacists

University of the State of New York – New York State Education Department. Collaborative Drug Therapy Management in NYS Pharmacist Credentials Required for Participation. Nysed.gov.

CDTM Application


Pharmacist Collaborative Drug Therapy Management Form

Application for Certification

Applicants Must Complete All Pages Of This Application In Ink

University of the State of New York – New York State Education Department. Collaborative Drug Therapy Management (CDTM). Nysed.gov.

- ➔ Signature on form must be made in presence of a Notary Public
- ➔ Must include document describing clinical activities with letter notarized by supervisor or practitioner collaborator

NYSCHP | New York State Council of Health-system Pharmacists

Poll Question

After this presentation I will consider the following:

NYSCHP New York State Council of Health-system Pharmacists

CDTM Pharmacist Role

NYSCHP | New York State Council of Health-system Pharmacists

Outpatient Cancer Centers

- **Multispecialty Team:**
  - Hematology/Medical oncology
  - Radiation medicine
  - Surgical oncology

- **Hematology/Medical Oncology Team:**
  - Physicians / Advanced Clinical Providers (ACP)
  - Nurses
  - Infusion pharmacists
  - Navigators
  - Medical assistants
  - Social workers
  - Financial staff
  - Secretaries
  - Schedulers
  - CDTM Clinical Pharmacists

Image From: Olivia; Your Ovarian Cancer Support. *AstraZeneca*. September 2023.

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Clinical Pharmacist Overview

- Provide comprehensive medication counseling
- Provide supportive care recommendations for adverse drug reactions
- Identify and assess barriers to medication adherence
- Conduct medication reconciliation, allergy review, and monitor drug-drug interactions
- Monitor parameters to ensure patient safety
- Perform prior authorizations (PAs) and appeals
- Collaborate with specialty pharmacies to facilitate medication acquisition
- Assist with high medication copayments

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Clinical Pharmacist Referral Process

- ACP / Physician Referral
  - Electronic medical record (EMR) task, call, text, verbal, etc.
- Check for CDTM consent form
- Prescribe medication to specialty pharmacy
- Assure scheduling team makes appointment with clinical pharmacist
  - In-person vs. Telehealth

NYSCHP | New York State Council of Health-system Pharmacists

Patient Assessment

- Assess for Medication Safety and Efficacy
  - Review current guidelines (i.e. National Comprehensive Cancer Network)
  - Assess labs, imaging, vitals, current medications and allergies
  - Determine drug-drug and food-drug interactions
  - Potential dose optimization
- Perform Comprehensive Medication Review
  - Patient & family members
  - Written and verbal education
  - Review medication acquisition process and treatment initiation date
- Prescribe Supportive Care Medications
  - Medication specific (antiemetics, creams, antidiarrheals)

NYSCHP | New York State Council of Health-system Pharmacists

Patient Education

- Patient education should include:
  - Diagnosis, goal, and duration of treatment
  - Drug name (generic and brand), dose, schedule
  - How the drug will be obtained
  - Potential side effects and management, including reproductive and fertility risks
  - Safe storage and handling and disposal of unused medication and safe handling of body secretions and waste
  - Potential interactions with food or drugs
  - Missed dose plan
  - Monitoring appointments
  - Information on how, when, who, and why to contact to report side effects
  - Refill process

NYSCHP | New York State Council of Health-system Pharmacists

The Oral Anticancer Medication Toolkit. ONS. 2023.

Follow-up

- Assure adequate patient follow-up once patient obtains new medication
  - Lab appointments
    - Medication specific (e.g. CBC, CMP, TSH, EKG)
  - MD/ACP follow-up
  - Pharmacist follow-up
    - 1-2 weeks after new medication initiation
    - In-person or telehealth

NYSCHP | New York State Council of Health-system Pharmacists

Clinical Pharmacist Follow-up

- Follow-up covers many topics:
  - Assessing adherence
    - Adherence and persistence rates for oral oncolytics vary from 50% to 100%
    - To maximize effectiveness of oral therapy, patients must adhere to their treatment
  - Providing individualized support to maintain optimal adherence
  - Assessing for side effects
  - Reinforcing education on self-care and when to report symptoms to healthcare team
  - Re-assessing drug administration (food-drug and drug-drug interactions)
  - Confirming next appointments
  - Reinforcing how and when to contact team

NYSCHP | New York State Council of Health-system Pharmacists

The Oral Anticancer Medication Toolkit. ONS. 2023.
Mackler E, et al. *ASCO*. 2018;15(4):e346-e355.

Barriers to Patient Adherence / Supportive Care

- Medication Cost
- Lack of initial education
- Lack of follow up/Adverse drug reactions
- Language/Physical/Cognitive barriers
- Living condition
- Social support/Cultural beliefs
- Lack of tailored guidance and services

NYSCHP | New York State Council of Health-system Pharmacists

Barriers to Patient Adherence / Supportive Care

Medication Cost	Assessment of medication access
Lack of initial education	Initial assessment
Lack of follow up/Adverse drug reactions	Periodic reassessments
Language/Physical/Cognitive barriers	Interpreter/Telehealth/Caregiver
Living condition	Referral to social worker
Social support/Cultural beliefs	Interactions with family/caregiver
Lack of tailored guidance and services	Tailored guidance and services

- Medication counseling/motivational interviewing sessions
- Patient tools (pills boxes, calendars, text messaging, etc.)

NYSCHP New York State Council of Health-system Pharmacists

Poll Question

What are the most common barriers to initiating oral oncolytics at your practice? (Select all that apply)

NYSCHP New York State Council of Health-system Pharmacists

Oral Cancer Treatments

- Oral anticancer drugs have become standard of care for several types of cancer
- Nearly half of newly launched oncology medications are taken orally
  - Chemotherapy
  - Targeted therapy
  - Hormonal Therapy
- Must be sent to **specialty pharmacies**
  - Limited distribution drugs
- Typically covered under prescription benefit
  - Usually high copayments

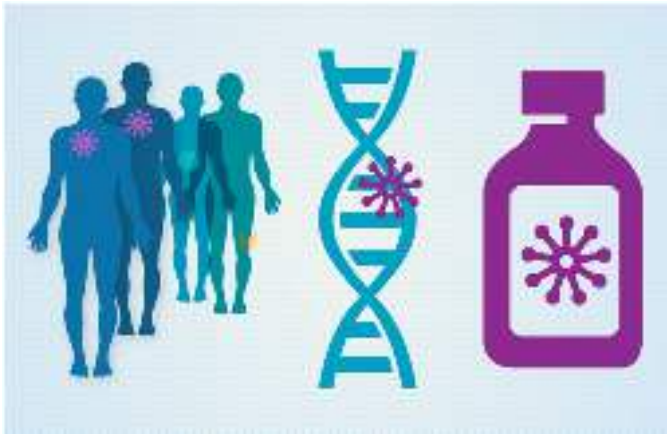


Image From: Targeted Therapy to Treat Cancer. *NIH*. May 2022.

NYSCHP | New York State Council of Health-system Pharmacists

Specialty Medications

- Specialty medications have complex regimens, high costs and can require special handling, administration and clinical follow-up
- Drug manufacturers contract with limited number of specialty pharmacies to dispense medications
- Specialty pharmacies in limited distribution must demonstrate ability to manage complex medications
  - Demonstrate their processes provide quality patient care
    - Provide therapy-specific patient management services, 24/7 patient and prescriber support, ensure safe and accurate dispensing practices, etc.
  - Obtain accreditation
    - Utilization Review Accreditation Commission (URAC)

Schwartz RN, et al. *JNCCN*. 2010;8(4):S1-S12.

NYSCHP New York State Council of Health-system Pharmacists

Specialty Pharmacies

- Typically mail order
- Patient's specialty pharmacy depends on:
  - Prescription insurance restrictions
    - i.e. Express Scripts must use Accredo Pharmacy
  - Pharmacy access to medication
    - limited distribution network (check manufacturer's website)
- Examples of specialty pharmacies include:
  - Accredo Specialty Pharmacy
  - BriovaRx
  - CVS Caremark Specialty
  - Onco360
  - Vivo Health Pharmacy
  - Walgreens Specialty

NYSCHP | New York State Council of Health-system Pharmacists

Specialty Pharmacy Challenges

- Oral anti-cancer medications are time sensitive
- Delays in starting therapy may occur if key information is not communicated with these pharmacies
  - Clinical Pharmacists play a key role in the medication acquisition process and work as liaisons with specialty pharmacies
- Need to consider time frame necessary for delivery and availability of mail/shipping services
- Medications are sometimes part of a bigger care plan that requires coordination
  - Medication plans require close communication with schedulers within medical and radiation oncology
    - Examples: oral chemotherapy plus radiation (chemo-RT) or intravenous and oral therapy concomitantly

Trapani D, et al. *ASCO. 2023*;43:1-13.

NYSCHP | New York State Council of Health-system Pharmacists

Prior Authorizations / Appeals

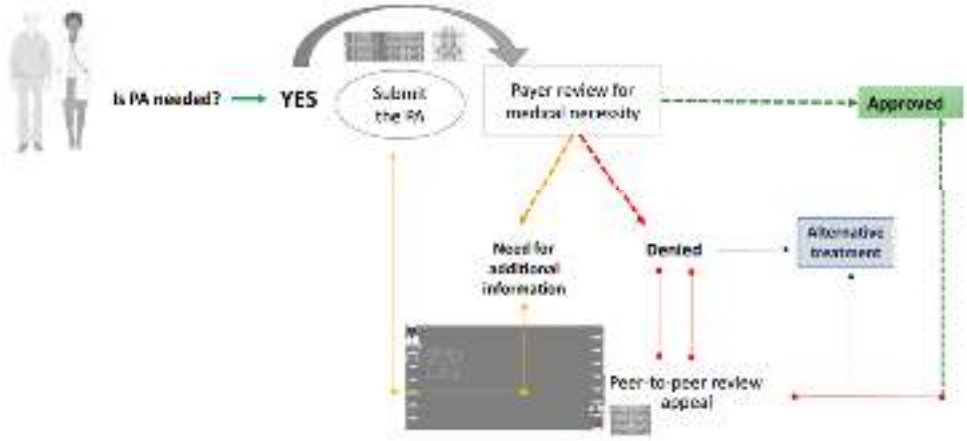
- Complicated PA processes can delay entirety of a patient's treatment plan
- As oncology medication pipeline continues to grow, providing clinical evidence for payer coverage becoming more complicated
  - Estimates show 30% of cancer therapies are off-label use
- Necessary documentation for PA approval can include:
  - Evidence from NCCN guidelines, peer-reviewed studies, or clinical trial guidelines
  - Clinical notes
  - Clinical rationale for why other treatments are not appropriate

NYSCHP | New York State Council of Health-system Pharmacists

Kalis JA, et al. *J Oncol Pract*. 2015;11(2):e139-43.

Prior Authorization Process

- Unknown if insurance company will require PA until processed at specialty pharmacy
- PAs can be completed through calling insurance company directly and faxing clinical notes or online via covermymeds.com
- Turnaround time for urgent PA can be 24-72 hours
- Denied PAs require appeals (letters of necessity or peer-to-peer reviews)
- If insurance denies appeal, consider free drug applications if available



NYSCHP | New York State Council of Health-system Pharmacists

Trapani D, et al. *ASCO*. 2023;43:1-13

High Medication Costs

- Prices of oral anticancer medications continue to increase
- Besides stress of cancer diagnosis, financial burden for patients and families is an additional factor
- Drug manufacturers are not able to legally provide assistance with cost sharing for patients who have government-sponsored insurance
- Patients with Medicare Part D could face very high copayments
- Patients with commercial insurance are faced with annual plan limits and coverage caps
- Potential of physicians having to choose intravenous or subcutaneous medications to avoid high out-of-pocket copays

Dusetzina SB. *N Engl J Med*. 2022;386(23):2164-2167.

NYSCHP | New York State Council of Health-system Pharmacists

Medication Copay Assistance

- Copay Cards
  - For patients with commercial insurance
  - Most manufacturers have drug-specific copay cards on their website
- Charity Programs / Foundational Assistance
  - Medicare and commercial plans accepted
  - Depends on patient diagnosis
  - Examples: Cancer Care, The Healthwell Foundation, Patient Assistance Foundation
- Free Drug
  - Patients with no insurance or **under**-insured
  - Search drug on Needymeds.org → "Patient Assistance Programs" → click link for website or enrollment form
  - Income-based (tax documentation is required)
  - Turnaround time 7-10 days
  - **Manufacturers currently limiting eligibility**

NeedyMeds
www.needymeds.org

NYSCHP | New York State Council of Health-system Pharmacists

Poll Question

How does your team/specialty pharmacy handle patients' financial toxicity (high co-pay/deductible, out-of-pocket expenses) when it comes to specialty medications coverage? (Select all that apply)

NYSCHP | New York State Council of Health-system Pharmacists

Example Patient

VM is a 79 yoF ovarian cancer. She is s/p 6 cycles of carboplatin and paclitaxol with complete response. She now requires maintenance therapy with PARPI (niraparib, olaparib, rucaparib). However, cost of these drugs averages between $16,000 - $19,000 per month.

➔ **Prescription Insurance:**

- Commercial (OptumRx) plan through Superior Officers Council
- Yearly prescription benefit cap of $10,000

➔ **Current Barriers:**

- Grant funding closed for indication
- Manufacturer Copay Cards will last only 1-1.5 months
- Patient ineligible for free drug programs (PAPs) due to current program restrictions (commercial insurance)
  - Appeals/letter of hardships for reconsideration not accepted

NYSCHP | New York State Council of Health-system Pharmacists

Temkin SM, et al. *First Report Managed Care*. 2018;15(7).

Current Legislative Issues

- **Federal**
  - Cancer Drug Parity Act
- **New York State**
  - CDTM bill

NYSCHP | New York State Council of Health-system Pharmacists

Cancer Drug Parity Act

- H.R. 6301/S.2039
- Oral anticancer treatment vs. IV chemotherapy
- Most *intravenous* anti-cancer treatments are covered under the medical component of health insurance plans
- O*rally administered* anti-cancer treatments are only covered under the more expensive prescription component of insurance plans
- Orally administered anti-cancer medications are **NOT** affordable under current laws

NYSCHP | New York State Council of Health-system Pharmacists

Cancer Drug Parity Act

- Out of pocket costs for oral chemotherapy
- Pharmacists help with medication access issues
- The Cancer Drug Parity Act would offer greater access, end the financial disparity between oral and IV chemotherapy reimbursement, and protect approximately 140 million patients from possible financial hardship

IV Treatment

Financial Stability

Oral Treatment

Financial Toxicity

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Restrictions in New York State (NYS)

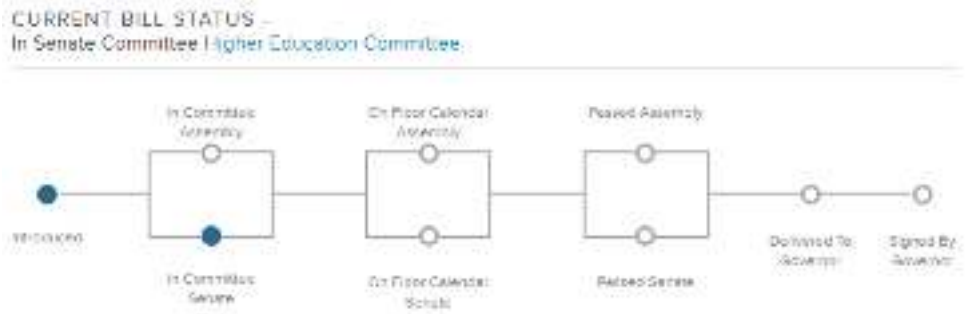
- Restricted to article 28 facilities
  - Teaching hospital or general hospital, including any diagnostic center, treatment center, or hospital-based outpatient department
  - Nursing home with an on-site pharmacy staffed by a licensed pharmacist
  - Both pharmacist/physician must be employees of facility
- Requires patient consent
- Law sunsets every 2 years

University of the State of New York – New York State Education Department. Collaborative Drug Therapy Management (CDTM). Nysed.gov.

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Current Legislative Bill in NYS

- Senate Bill S4043 / Assembly Bill A9702
- Bill Purpose:
  - Makes permanent the law which authorizes CDTM permanent
  - Adds Nurse Practitioners (NPs) as a provider of services for purposes of CDTM
- Referred to High Education - 2026



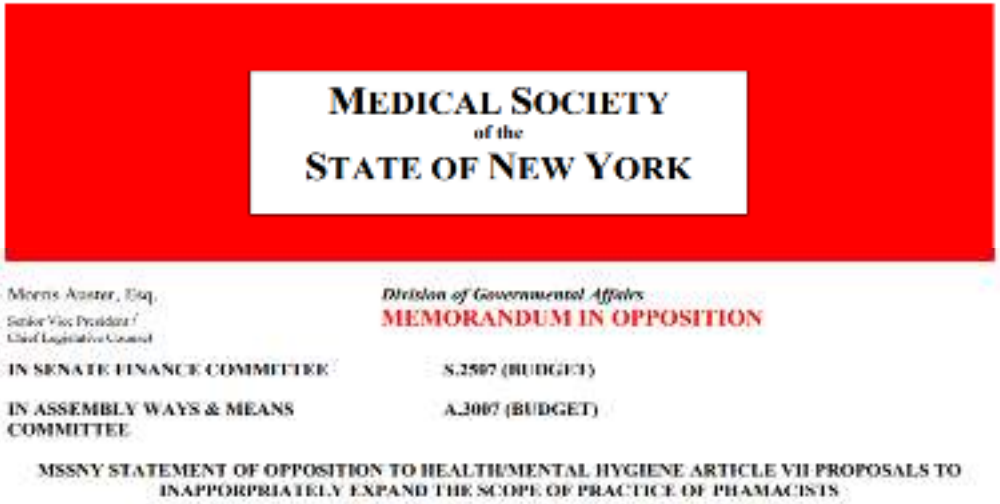
New York State Council of Health-system Pharmacists. Collaborative Drug Therapy Management (CDTM). Nyschp.org.

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Oppositions

➔ "Physician-pharmacist CDTM protocols are too premature to add NPs"

➔ "NPs do not have the sufficient pharmacology background to successfully work with pharmacists by themselves on managing patient medications (and potential interactions) on a large scale basis"



MEDICAL SOCIETY
of the
STATE OF NEW YORK

Morris Auster, Esq.
Senior Vice President /
Chief Legislative Counsel

Division of Governmental Affairs
MEMORANDUM IN OPPOSITION

IN SENATE FINANCE COMMITTEE — S.2507 (BUDGET)

IN ASSEMBLY WAYS & MEANS COMMITTEE — A.3007 (BUDGET)

MSSNY STATEMENT OF OPPOSITION TO HEALTH/MENTAL HYGIENE ARTICLE VII PROPOSALS TO INAPPORPRIATELY EXPAND THE SCOPE OF PRACTICE OF PHAMACISTS

NYSCHP | New York State Council of Health-system Pharmacists

CDTM Oncology Pharmacist Impact

NYSCHP | New York State Council of Health-system Pharmacists

Integrated Payment Model for Clinical Pharmacists: Program Overview

Michigan Pharmacists Transforming Care and Quality (MPTCQ)

Program description: Development and implementation of a statewide provider-payer program for services performed by clinical pharmacists

Program goals:

- Primary goal: Improve patient care and outcomes related to Medicare star ratings and HEDIS* measures through integration of clinical pharmacists into direct patient care
- Short term: Adopt and modify integrated pharmacist practice payment model
- Long term: Develop a sustainable model of pharmacist integration at physician organizations to improve patient care and outcomes

Services provided:

- Diabetes, hypertension, hyperlipidemia and comprehensive medication review with plans to expand clinical services at POs**

*HEDIS = **Healthcare Effectiveness Data and Information Set**
****PO = Physician Organizations**

Choe HM, et al. *J Manag Care Spec Pharm*. 2018;24(4):373-378.

NYSCHP | New York State Council of Health-system Pharmacists

Integrated Payment Model for Clinical Pharmacists: Study Overview

Objective

- To evaluate a statewide program, Michigan Pharmacists Transforming Care and Quality (MPTCQ), that incorporated pharmacists within 17 POs

Methods

Time period

- Data collected from June 2016 to September 2018
- Cohort 1 started in July 2016 with 10 POs
- Cohort 2 started in October 2016 with 7 POs

Process outcomes

- Number of participating POs
- Patient encounters
  - DSM/CMR*
  - Number, type, reason for medication changes
  - Medication adherence, cost barriers
- Average visits per patient

Clinical outcomes

- Hemoglobin A1c and blood pressure change

*DSM/CMR = Disease State Management/Comprehensive Medication Review

NYSCHP | New York State Council of Health-system Pharmacists

Integrated Payment Model for Clinical Pharmacists: Study Results

Results

- 17 POs (16 retained their pharmacists at the end of funding)
- Pharmacists made 15,153 therapeutic medication changes during visits for diabetes and hypertension, with approximately 70% related to efficacy.
- Pharmacists completed 4,203 CMR visits for 3,092 patients.
- During CMR visits, 1,296 therapeutic medication changes were recommended.
- Problems with medication cost were identified in 13% of CMR visits.
- Blood pressure and A1c levels decreased in patients managed by pharmacists:
  - Group 1 (initial SBP 140-159 mmHg, DBP <90 mmHg) included 109 cohort 1 patients with an average SBP change of −4.3 (range −37-38) and 149 cohort 2 patients with an average SBP change of −5.6 (range −50-38).
  - Group 2 (initial SBP 140-159 mmHg, DBP ≥90 mmHg) included 66 cohort 1 patients with an average SBP change of −11 (range −40-30) and DBP change −11.2 (range −42-10), and 61 cohort 2 patients with an average SBP change of −12.1 (range −44-18) and DBP change −9.7 (range −40-12).
  - Group 3 (initial SBP ≥160 mm Hg, DBP <90 mmHg) included 30 cohort 1 patients with an average SBP change of −23.2 (range −76-18) and 31 cohort 2 patients with an average SBP change of −24.6 (range −52-10).
  - Group 4 (initial SBP ≥160 mmHg, DBP ≥90 mmHg): an average SBP change of −30.1 (range −66-6) and DBP change of −14.7 (range −38-10), and cohort 2 patients with an average SBP change of −26.5 (range −100-19) and DBP change of −14.8 (range −50-12).
  - HgA1c: (Cohort 1 average of -1.9% after initial Hg of >=9%; Cohort 2 average of -2.5% after initial Hg of >=9%)

Conclusion

- A statewide provider-payer partnership successfully integrated and retained primary care pharmacists within POs.
- Pharmacists in the MPTCQ program contributed to improvements in disease control by changing medications to improve patient clinical outcomes

*DSM/CMR = Disease State Management/Comprehensive Medication Review

NYSCHP | New York State Council of Health-system Pharmacists

Other Studies

Title	**Implementation and outcomes of a pharmacist-led CDTM for oncology symptom management[1]**
Background	Optimization of cancer patients symptom control by pharmacists by Michigan Oncology pharmacists.
Methods	Using CDTM program, oncology pharmacists provided management of gastrointestinal toxicities secondary to a patient's cancer diagnosis.
Outcomes/ Results	The total number of visits = 136. The total number of interventions = 169. Most interventions (100/169, 59.2%) were related to nausea/vomiting. Most patients (69.2%) had a reduction in the severity of their referral diagnosis symptom(s).
Conclusion	The CDTM program allowed pharmacists to independently manage gastrointestinal toxicities of patients with cancer and improved patient symptom severity.

Clinical outcomes

Homan MJ, et al. Support Care Cancer. 2021;29(11):6505-6510.

NYSCHP | New York State Council of Health-system Pharmacists

Other Studies

Title	**The clinical and financial impact of remote clinical oncology pharmacist engagement in community-based practices within The US Oncology Network[2]**
Background	Demonstration of significant financial impact for the practice, payers, and patients.
Methods	The ClinReview pharmacist electronically reviewed recently placed or modified chemotherapy regimen orders within a community oncology practice.
Outcomes/ Results	Total interventions = 5716: Clinical impact on the patient (36%), dose rounding (35%) and therapeutic interchange (30%). Overall, interventions improved the cumulative practice margins by $1,455,033 and reduced total medication costs by $5,962,551. The average program return on investment was 415% (range 100–915%) over 12 months.
Conclusion	An oncology clinical pharmacist is a cost-effective and valuable member of the care team in community oncology practice.

Financial outcomes

J Oncol Pharm Pract. 2024;30(1):165-172

NYSCHP New York State Council of Health-system Pharmacists

Other Studies

Title	**Risk factors predicting clinical oncology pharmacists' medication modifications[3]**
Background	Identification of patient characteristics that were associated with medication modification.
Methods	Using CDTM program, oncology pharmacists predicted medication modification interventions based on age and rurality using zero-inflated Poisson regression.
Outcomes/ Results	Individuals residing in rural/small towns compared to metropolitan were more likely to have greater numbers of medication modifications (0.545 SE 0.10, p<0.001). Age (X2=10.2, 3df, 0=0.017) and rurality (X2=78.81, 6df, p<0.001) were statistically significantly associated with more medication modifications.
Conclusion	Patients who are older, and living in more rural communities were more likely to receive medication modifications.

Disparity-related outcomes

JCO Oncol Pract 19, 54-54(2023.

NYSCHP | New York State Council of Health-system Pharmacists

Poll Question

What is your impact as a clinical pharmacist on a daily basis (more than 20% time spent)? (Select all that apply)

NYSCHP New York State Council of Health-system Pharmacists

Conclusion

- CDTM credentialed clinical pharmacists in an outpatient cancer center can:
  - Enhance patient care through optimized drug therapy management
  - Increase patient involvement in care
  - Decrease drug-related problems (adverse drug reactions, drug interactions, adherence, etc.)
  - Prevent treatment delays by increasing medication access
- Continued recording of pharmacy activities can:
  - Demonstrate the clinical impact of CDTM pharmacists and help further the development of collaborative practice agreement
  - Potentially provide a foundation for reimbursement for services in the future

NYSCHP | New York State Council of Health-system Pharmacists

References

1. Choe HM, Lin AT, Kobernik K, et al. Michigan Pharmacists Transforming Care and Quality: Developing a Statewide Collaborative of Physician Organizations and Pharmacists to Improve Quality of Care and Reduce Costs. *J Manag Care Spec Pharm*. 2018;24(4):373-378. doi:10.18553/jmcp.2018.24.4.373
2. Homan MJ, Reid JH, Nachar VR, et al. Implementation and outcomes of a pharmacist-led collaborative drug therapy management program for oncology symptom management. *Support Care Cancer*. 2021;29(11):6505-6510
3. *Collaborative Drug Therapy Management (CDTM)*. NYS Pharmacy:Collaborative Drug Therapy Management (CDTM). https://www.op.nysed.gov/professions/pharmacist/collaborative-drug-therapy-management
4. Mackler E, Segal EM, Muluneh B, Jeffers K, Carmichael J. 2018 Hematology/Oncology pharmacist association best practices for the management of oral oncolytic therapy: pharmacy practice standard. *J Oncol Pract*. 2019;15(4):e346-e355.
5. Mackler ER, Reyes-Gastelum D, Young K, Wietzke J, Schwartz A, Farris KB. JCO Oncology Practice 2023 19:11_suppl, 54-54
6. Schwartz RN, Eng KJ, Frieze DA, Gosselin TK, Griffith N, Seung AH, Hinkel JM, Johnson PE, Johnson SA, Li EC, Szabatura AH, Wong MK. NCCN task force report: specialty pharmacy. *J Natl Compr Canc Netw*. 2010;8 Suppl 4:S1-12.
7. Carroll M, Koselke E, Howell J, et al. The clinical and financial impact of remote clinical oncology pharmacist engagement in community-based practices within The US Oncology Network. *J Oncol Pharm Pract*. 2024;30(1):165-172
8. Kalis JA, Pence SJ, Mancini RS, Zuckerman DS, Ineck JR. Prevalence of off-label use of oral oncolytics at a community cancer center. *J Oncol Pract*. 2015;11(2):e139-43.
9. Trapani D, Kraemer L, Rugo HS, Lin NU. Impact of prior authorization on patient access to cancer care. *Am Soc Clin Oncol Educ Book*. 2023;43:e100036.
10. Dusetzina SB. Your money or your life – the high cost of cancer drugs under Medicare part D. *N Engl J Med*. 2022;386(23):2164-2167.
11. Oral Anticancer Medication Toolkit. Oncology Nursing Society. ons.org. https://www.ons.org/clinical-practice-resources/oral-adherence-toolkit.
12. Temkin SM, Dizon D. PARP inhibitors for ovarian cancer: Who and when, and can we afford it? *First Report Managed Care*. 2018;15(7).

NYSCHP | New York State Council of Health-system Pharmacists

Collaborative Drug Therapy Management in Ambulatory Oncology

Speakers

Lilia Davenport

PharmD, BCPS, BCOP

Clinical Pharmacy Manager and Oncology Pharmacotherapy Specialist

The Brooklyn Cancer Center

The Brooklyn Hospital Center

Samantha Paone

PharmD, MBA, BCPS

Ambulatory Hematology/Oncology Clinical Pharmacy Specialist

Staten Island University Hospital

Northwell Health

NYSCHP New York State Council of Health-sy Pharmacists

Billing

"Incident-to" Billing:

- For services that are furnished incident-to physician professional services in the physician's office (i.e. non-facility clinics)
- Includes physician owned outpatient practices or hospital affiliated practices with a different tax identification number than the hospital
- Governed by a number of CMS rulings
  - Pharmacists can only bill Level 1 – CPT code 99211
    - No requirements for documentation elements, should address evaluation and management
- Process on paper or electronic CMS 1500 claim form
- Pharmacist would not want to see and bill patient on same day as physician visit in same office or clinic - CMS will pay the lesser of the two bills
- Ask what Level providers are already billing at; if same-day visits with providers are Level 3 or 4, see if they can bill a Level 5 for adding a pharmacist to the visit

Facility fee Billing:

- For hospital-based outpatient services that are hospital-owned facilities
- Hospital Outpatient Prospective Payment System
- Single flat rate; G0463 code signifies a "Hospital Outpatient Clinic Visit for Assessment & Management of a Patient"
  - Represents the expense of the hospital's resources for the visit
- No established criteria for documentation
- Usually done on the CMS 1450 form or the 837I (electronic version of form) with supervising physician's NPI

NYSCHP | New York State Council of Health-system Pharmacists