Operationalizing Guideline Medication Management – Exploration of Collaborative Practice Pharmacist

Jeremy K.W. Spiewak, PharmD, RPh, MSCS
Ambulatory Care Clinical Pharmacy Specialist
Beth Israel Lahey Health
Lahey Inflammatory Bowel Disease Center
Massachusetts

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Learning Objectives

At the end of this session, participants should be able to:

1. Recall the role of collaborative practice pharmacists in longitudinal follow-up and medication management of patients with specialty disease states
2. Identify elements of a specialty clinic Ambulatory Care Pharmacist (ACP) collaborative practice agreement
3. Recognize strategies for ACPs to collaborate efficiently within interdisciplinary teams to decrease administrative burden, increase access to care and lead to improved outcomes

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EVOLVING ROLE OF THE PHARMACIST

Collaborative Practice Pharmacist
Specialty Chronic Disease State Management

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Expanding Role of Pharmacist

- Traditional scope of practice:
  - Indications, Dosing, Pharmacokinetics/Dynamics
  - Adverse reactions/Side effects/Risks associated with therapy
  - Compounding
  - Marketing
  - “Benching” – fulfillment/order verification
  - Medical Science
  - Investigational Drug Service
  - Managed Care
  - Others not mentioned

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Expanding Role of Pharmacist, cont'd.

- As we increase our knowledge & focus on a strategy of patient-centric care
  - Pharmacogenomics
  - Vaccinators – 1994/1996 with expanding authority for protocolized evaluation & standing orders
  - Insurance navigators & white glove fulfillment
  - Point of care testing & treatment
  - Wellness screenings
  - Consultant
  - Collaborative Practice Agreements (CPAs) & more

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How did we get here?

- Complexities beyond classes of “inducers” & “inhibitors” with medical therapies
- Organic advancements in technology – availability of point of care testing
- Advancements in health/disease state knowledge
- Pharmaceutics/delivery vehicle improvements & new discoveries
- Some would argue the curriculum of the PharmD program
- List is endless

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Definition of a CPA

"A Collaborative Practice Agreement is a formal agreement in which a licensed provider makes a diagnosis, supervises patient care and refers the patient to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions."

Source: Centers for Disease Control and Prevention. Collaborative Practice Agreement and Pharmacists' Patient Care Services. Cent Dis Control Prev. 2013:8. https://www.cdc.gov/dhdsp/pubs/docs/Translational_Tools_Pharmacists.pdf

CPA Functions

- Functions most often cited:
  - Comprehensive Medication Management
  - Transitions of Care
  - Refill Extension
  - Therapeutic Interchange
  - Ordering, Interpreting and Monitoring Labs

Source: Centers for Disease Control and Prevention. Collaborative Practice Agreement and Pharmacists' Patient Care Services. Cent Dis Control Prev. 2013:8. https://www.cdc.gov/dhdsp/pubs/docs/Translational_Tools_Pharmacists.pdf

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Roles of Pharmacists & Associated Settings

- Administrative Clinical Pharmacist – Logistics & Clinical Pharmacy
- Specialty Pharmacist – Fulfillment Logistics & Clinical Pharmacy
- Traditional Ambulatory Care Pharmacist Core – Pharmacist Clinician
- **Ambulatory Care Pharmacist CPA Specialty – Pharmacist Clinician**

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Overview of Administrative Clinical Pharmacist – Logistics/Clinical

Therapy Plan Pull-Through

1) M.D. evaluation & prescribing sent to Specialty Pharmacy for benefit investigation

2) Coverage determination seeks clinical support, RPh provides rationale (LOMN, peer to peer, etc.)

3) Barriers to care addressed with RPh support

4) Fulfillment addressed with Specialty Pharmacy & clarifications provided by RPh

5) Patient receives therapy & RPh provides consultation

Rx refills, monitoring, re-auths per protocol

Source: Bagwell A, Kelley T, Carver A, Lee JB, Newman B. Advancing Patient Care Through Specialty Pharmacy Services in an Academic Health System. J Manag Care Spec Pharm. 2017 Aug;23(8):815-820. doi: 10.18553/jmcp.2017.23.8.815. PMID: 28737983; PMCID: PMC10398086.

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Overview of the Specialty Pharmacist – Fulfillment Logistics/Clinical

Life Cycle of SPRx

1) M.D. evaluation & prescribing
2) Specialty Pharmacy benefit investigation
3) Insurance coverage determination
4) Specialty RPh initial assessment & addresses barriers
5) Specialty Pharmacy Rx fulfillment
6) Patient receipt of Rx

Source: ASHP Specialty Pharmacy Resource Guide. ASHP, Dec 2015. https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/specialty-pharmacy/specialty-pharmacy-resource-guide.ashx?la=en&hash=C38B8C24693D80CAE2377DC21FF0BB613424CE3D

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Overview of Traditional Ambulatory Care Pharmacist Core – Clinician

ACP Chronic Disease Management

1) M.D. evaluation, prescribing & referral to ACP

2) ACP establishes care with patient, evaluates, educates & sets cadence of follow up

3) ACP follow up & optimizes therapy as applicable

4) ACP monitors treatment plan for safety & efficacy

5) ACP performs limited physical assessments

6) Patient health outcomes achieved

Source: FAQ: Basics of Ambulatory Care Pharmacy Practice. ASHP Ambulatory Care Practitioners, July 2019. https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/ambulatory-care/basics-of-ambulatory-care-pharmacy-practice

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Concerns of Scope Creep

- We need to be conscious that just as all other providers may have specialization, some pharmacists also may have specialized training
- Just as we choose the right drug, with the right specifications, at the right time, we also need to have guard rails in place to ensure the right pharmacist initiates practice, within the right specialty, and with the right oversight/monitoring: RPh Limitations of Scope
- The role of the CPA is not designed to replace Physician/Advanced Practitioner visits, but as adjunct to qualitatively improve patient outcomes and achieve clinic goals

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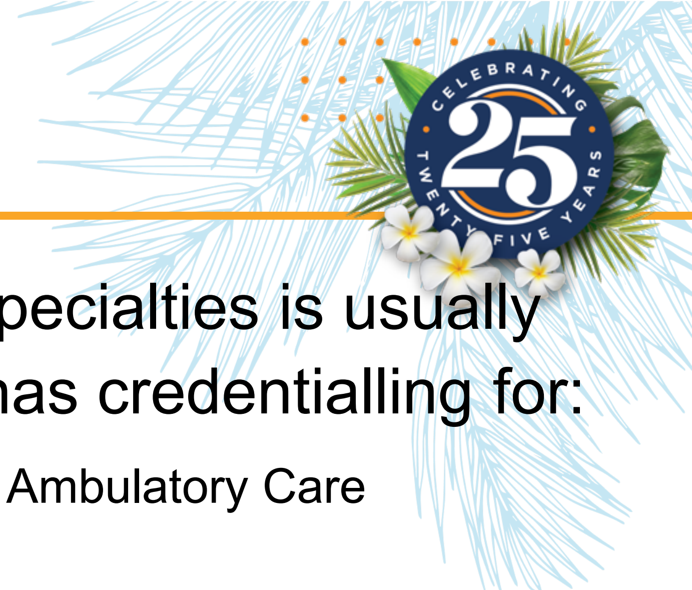
“Qualified” Definition



- No defined federal qualifications, though states recognize CPAs with variation
- The American Society of Health-System Pharmacists (ASHP) has some minimum qualifications for consideration & this is reflected in some state laws

- Board of pharmacy specialties is usually the gold standard & has credentialling for:
  - BCACP – Board Certified Ambulatory Care Pharmacist
  - BCPS – Board Certified Pharmacotherapy Specialist
  - BCOP – Board Certified Oncology Pharmacist
  - BCGP – Board Certified Geriatric Pharmacist
  - BCPP – Board Certified Psychiatric Pharmacist & others
- Other usual qualifications include PGY-1 & sometimes PGY-2 residency

Source: FAQ: Basics of Ambulatory Care Pharmacy Practice. ASHP Ambulatory Care Practitioners, July 2019. https://www.ashp.org/-/media/assets/pharmacy-practice/resource-centers/ambulatory-care/basics-of-ambulatory-care-pharmacy-practice

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State Requirements

247 CMR: BOARD OF REGISTRATION IN PHARMACY

247 CMR 16.00: COLLABORATIVE DRUG THERAPY MANAGEMENT

Section

16.01: Purpose
16.02: Pharmacist Qualifications
16.03: Practice Setting Requirements
16.04: Collaborative Practice Agreements - Required Agreement Terms for All Practice Settings; Duties; Biennial Renewal; Termination; Agreement to Be Filed in Primary Practice Setting; Employment Relationships
16.05: Authority of Board of Registration in Medicine

16.01: Purpose

247 CMR 16.00 sets forth criteria applicable to pharmacists and pharmacies that engage in collaborative drug therapy management with physicians in accordance with M.G.L. c. 112, §§ 24½ and 24¾, including pharmacist qualifications, and requirements for practice settings and collaborative practice agreements.

16.02: Pharmacist Qualifications

(1) In accordance with M.G.L. c. 112, § 24B½, subsection (b), to qualify to enter into a collaborative practice agreement and engage in collaborative practice, a pharmacist must:

(a) hold a current unrestricted license in good standing to practice pharmacy in the Commonwealth and currently be engaged in pharmacy practice in the Commonwealth;

(b) maintain at least $1,000,000 (per occurrence) of professional liability insurance during the term of the agreement which specifically covers drug therapy management;

(c) have completed five years of experience as a licensed pharmacist or have satisfied one of the requirements in 247 CMR 16.02(1)(c)1. through 2.:

1. have earned a doctor of pharmacy degree and have entered into a collaborative practice agreement on or before June 30, 2017; or

2. have completed such other education or residency criteria that the Board determines to be the equivalent of five years experience as a licensed pharmacist;

Source: 247 CMR 16.00

- Ensure adequate research prior to proposal
  - Specifically: CPA qualifications, terms & functions vary from state to state
- Use state board for verification
- All 50 states recognize some form of CPA
  - Aug. 2023 Delaware was the final to pass legislation recognizing CPA RPh

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Benefits of CPA

- Simply having regular contact with the pharmacists allowed other healthcare issues to be identified & addressed
- Population health standpoint
- Operationalizing guideline chronic disease management
- P&T Committee presentations to advocate for practice needs
- Immediate point of contact for medication related concerns
- Embedded vaccination champion

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Prescribing by Pharmacist

- Requirements vary from state to state
- Not every state recognizes/authorizes RPh prescribing
- May need to have RPh "authorize prescription on behalf of"
- Massachusetts General Law. c. 94C, s. 18(e) requires that all medical personnel prescribing any medication must complete during each license renewal period at least one (1) hour of training on opioid abuse every year.

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Support for Prescriptive Authority

- Pharmacist led intervention → Pharmacist written prescription
- Accountability tracking through discrete fields
- Highest level of trust & operation at the top of RPh license
- Support/validation as pharmacist prescriber
- Performance Improvement
  - Prospective DUR review
  - Pharmacist to Pharmacist notes on Rx reduce clarification delay
  - Insurance navigation

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Overview of Ambulatory Care Pharmacist CPA Specialty – Pharmacist Clinician

ACP Specialty Disease Management

1) M.D. A&P & referral to ACP

2) ACP establishes care with patient & initiates therapy plan, follow up & optimizes therapy, as applicable

3) ACP monitors treatment plan for safety & efficacy along with limited physical assessments

4) ACP charts clinical rationale & support for therapy modifications/ continuations

5) ACP is a direct provider resource available to mitigate managed care/access barriers

6) Patient health outcomes achieved

Source: Atar D., Birkeland K.I., Uhlig T. 'Treat to target': Moving targets from hypertension, hyperlipidaemia and diabetes to rheumatoid arthritis. Ann. Rheum. Dis. 2010;69:629–630. doi: 10.1136/ard.2010.128462. .

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Assessment Question #1

Which of the following is NOT part of the role of a collaborative practice pharmacist in longitudinal follow-up with patients with specialty disease states?

A) Evaluating with Assessment and Plan

B) Prescribing add on therapies as required

C) Ordering labs for monitoring/evaluation

D) Diagnosing the patient

E) Assessing goals of therapy

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Answer Question #1

Which of the following is NOT part of the role of a collaborative practice pharmacist in longitudinal follow-up with patients with specialty disease states?

A) Evaluating with Assessment and Plan

B) Prescribing add on therapies as required

C) Ordering labs for monitoring/evaluation

D) Diagnosing the patient

E) Assessing goals of therapy

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OVERVIEW OF THE SPECIALTY CLINIC ACP COLLABORATIVE PRACTICE AGREEMENT

Framework &
P&T Considerations

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Planning Involved

- After identifying what functions are permitted in your state, identify your program goals:
  - Cost control
  - Performance improvement
  - Patient satisfaction
  - Rx pull-through & med access
  - Pharmacist-led outcomes data

- Recommend
  - Begin with identification of current state of RPh involvement in care process
  - Ensure there is an adequate plan to continue these crucial care points
  - Set up a meeting with key stakeholders to identify these goals

Source: 2020 Medication Access Report: Executive Summary. CoverMyMeds LLC, 2020. https://assets.ctfassets.net/2in405srp47m/4SyH0ZdIFQwuAuCzhuAmTo/973d7b3266a843c94c074fce698de9ea/CMM_36517_MARExecutiveSummary_Digital.pdf

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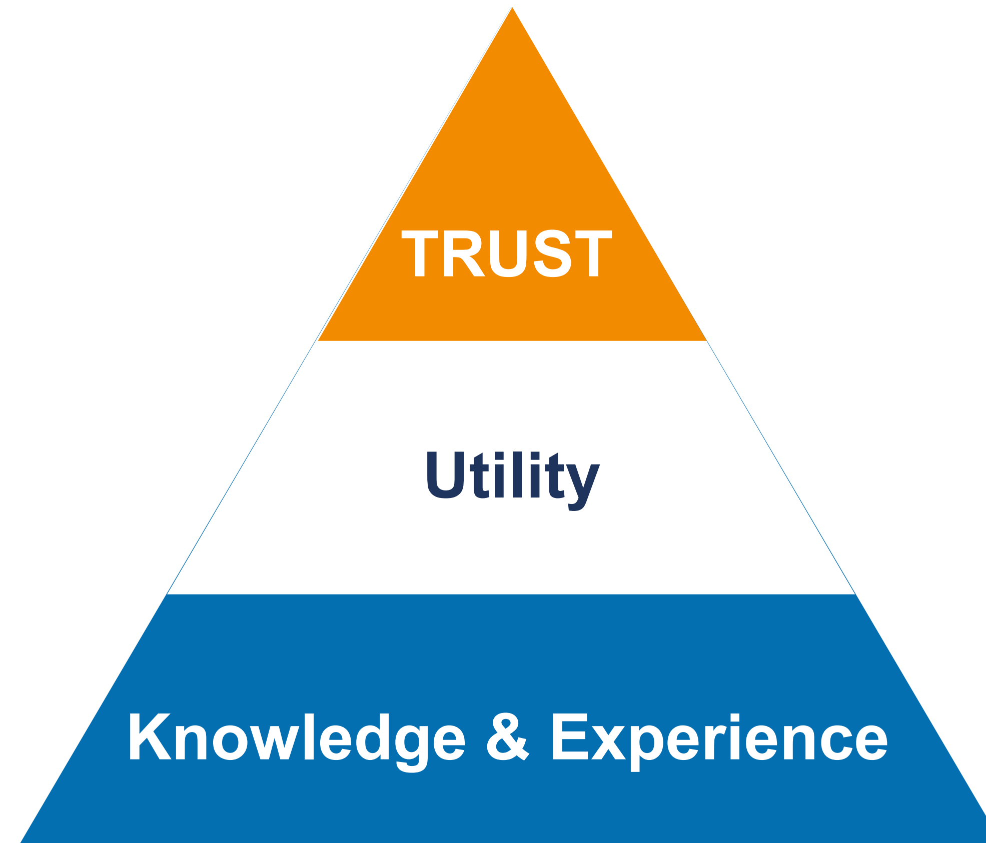
CPAs Operate on



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Stakeholders' Meetings

- Need to involve all key members
- This usually includes
  - Regulatory Affairs
  - Health Information Technology/EMR/IT
  - Practice Management – Supervisor, Admin, Scheduling
  - Proposed Supervising Physician
  - Chair of Department in Health Systems
  - Pharmacy Leadership
  - Population Health/Performance Network
  - Proposed Ambulatory Care Pharmacist Team

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Planning, cont'd.

- Review CPA objectives & ensure they align with practice/health system
- Be prepared to discuss concerns related to:
  - Credentials – Knowledge & experience (along with labeled credentials)
  - Interprofessional collaboration opportunities & care gaps to close
  - Liability – Qualitatively lower as more coordination of care
  - Operational workflow – Referral process, scheduling, ordering, follow up, contact

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CPA Required Terms

(2) Required Agreement Terms for All Practice Settings. In addition to specific practice setting collaborative practice agreement requirements, pursuant to 247 CMR 16.03, and in accordance with M.G.L. c. 112, § 24B¾ and 243 CMR 2.12, all collaborative practice agreements must also include:

(a) specific disease state(s) being co-managed, with each disease state identified as either primary or co-morbid;

(b) specific pharmacist prescribing authority pursuant to the CDTM agreement;

(c) detailed practice protocols;

(d) description of risk management activities;

(e) documentation of any initiation, modification or discontinuation of a patient's medication in the patient's permanent medical record;

(f) description of outcome measurements;

(g) detailed informed consent procedures appropriate to the practice setting;

(h) detailed procedures and periods by which time any test results, copies of initial prescriptions, modifications or discontinuances, copies of the patient consent and the CDTM agreement, and other patient information will be forwarded by the authorized pharmacist to the supervising physician, and a specific procedure for the authorized pharmacist to identify and transmit any urgent communications; description of the nature and form of the super-vision of the authorized pharmacist by the supervising physician, and a description of the procedure to follow when either the authorized pharmacist or supervising physician is unavailable or absent;

(i) the authorized pharmacist's attestation of satisfaction of the qualifications listed in 247 CMR16.02(1) for participating in collaborative drug therapy management; and

(j) the supervising physician's attestation of satisfaction of the qualifications listed in 243 CMR 2.12 for participating in collaborative drug therapy management.

- Address all required sections in the CPA
- Avoid extremely narrow/specific language
- Avoid language referencing specific texts/versions
- Reference general positions as opposed to people

Source: 247 CMR 16.00 (2)

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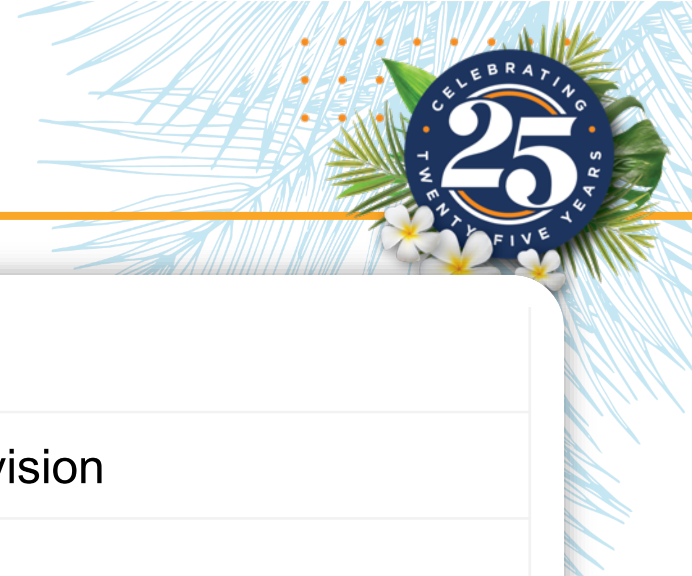
CPA Outline



Purpose	Disease state managed & providers involved
Referrals	Procedure for referrals to CPA clinic, patient consent & supervision
Clinic Visit	Details of RPh evaluation & clinical functions
Therapy Mgmt	Pharmacotherapy management functions
Monitoring	Laboratory orders & follow-up cadence
Counseling	Disease state/therapy plan counseling along with internal referrals for co-morbidities
Documentation	Service discharge, documentation & communication procedures
Goals	Outcome measures/quality assurance, risk mitigation & term renewal

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Framework

Beth Israel Lahey Health
Collaborative Drug Therapy Management Agreement

Inflammatory Bowel Disease

In accordance with *247 CMR 16.00: Collaborative Drug Therapy Management* and local institutional policies as applicable, an authorized Clinical Pharmacy Specialist may initiate, monitor, modify, and discontinue a patient's drug therapy in collaboration with physicians. By signing this document, the Department Chair (or designee) signs on behalf of all of the physicians within their department as the Supervising Physician. The Supervising Physician and pharmacist at the institution agree to enter into a Collaborative Practice for the management of Inflammatory Bowel Disease in patients according to the attached agreement.

The following agreement does not replace clinical judgment, and treatment goals and algorithms will follow the most current disease state guidelines.

Approved by: BILH Ambulatory P&T:
[institution] P&T (or appropriate local governing body):
[institution] Medical Executive Committee (or appropriate local governing body):

Revisions approved by:

Effective date:

- Purpose of CPA & disease state managed
- Followed by reference to the credentialed RPh & supervising M.D.

Source: Beth Israel Lahey Health data. Not for reuse without permission of Beth Israel Lahey Health

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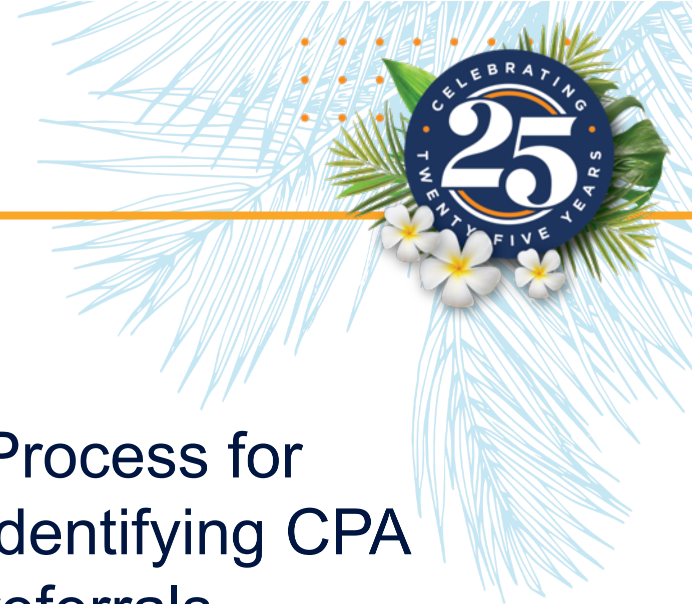
Patient Criteria – Referral & Dx



B. Referral to the Clinical Pharmacy Specialist (CPS)

1. Only patients receiving care at a BILH facility may be referred to a CPS credentialed to enter in to a collaborative practice agreement.
2. Initial visit with a CPS requires a referral by a BILH attending physician or advanced practitioner. The reason for referral (e.g. disease state, polypharmacy, etc) must be stated.
    1. Referrals for management by an embedded ambulatory pharmacist must originate in the department with the embedded pharmacotherapy clinic.
    2. Referrals for management through a remote monitoring pharmacotherapy clinic may originate in any BILH practice.
3. Attendance at scheduled pharmacist appointment constitutes patient consent to engage in CDTM.
4. The authorized pharmacist will perform the activities outlined in this agreement under indirect physician supervision defined as the supervising physician or his/her designee must be on facility premises or readily available by telephone.

- Process for identifying CPA referrals
- Initial visit/Dx from physician or advanced practitioner
- Patient Consent
- Provider Supervision

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CPA Clinic Procedures

C. Procedure

1. The approach to management of patients with Inflammatory Bowel Disease will follow the most recent BILH System guideline, local institution guideline, national guidelines, sound evidence, and clinical judgment.

2. Clinic visit
    a. Review the medical record including past medical history, family history, social history, allergies, current and past laboratory and other relevant test results and medications.
    b. Perform targeted physical assessment, which may include, but is not limited to obtaining vital signs (weight, blood pressure and pulse).
    c. Analyze relevant baseline tests as necessary.
    d. Review treatment goals specified by referring provider or determined at the clinic visit based on patient specific characteristics and evidence-based practice, including current guidelines.
    e. Medical emergencies
        i. For medical emergencies, the CPS will follow the appropriate local institution policies.
        ii. For non-emergency acute medical issues, the patient will be reviewed by a supervising physician or triaged through the referring physician's nurse triage system as appropriate.
        iii. For non-urgent medical issues outside the scope of the pharmacotherapy visit, the patient will be encouraged to follow up with his or her physician, and an appointment will be scheduled either through the CPS, the appointment scheduler, or the physician's secretary.

- What RPh Clinic visit looks like – details on activities & function
- Clear emergency protocol

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CPA Clinic Procedures (cont.)

3. Pharmacotherapy
   a. The CPS will evaluate and optimize pharmacotherapy including initiation, modification, and discontinuation of therapy per the referenced standard of care national guideline, or newly updated version since last approval
   b. Therapy will be initiated with first-line medication based on current guidelines. An alternative agent may be used if there is a compelling indication, if a contraindication exists, if the patient is already on a preferred regimen, or for financial considerations of the patient.
4. Monitoring: Therapy will continue to be tailored based on individual patient needs and clinical circumstances.
   a. Relevant tests will be ordered and results will be addressed by the CPS, as necessary for the monitoring of the therapeutic and toxic effects of medications based on the referenced guideline.
   b. Follow up visits will be scheduled as clinically appropriate.
   c. Referring provider will be notified of new findings or problems that are not resolving as anticipated.

- Therapy modifications & factors driving these decisions
- Therapy plan monitoring with associated laboratory orders, follow up & supervisor notification

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CPA Clinic Procedures, cont'd.

5. Patient counseling
   a. Provide education regarding the pathophysiology and complications of Inflammatory Bowel Disease, goals of therapy, mechanism of action of medications prescribed, proper administration and storage of medications, potential side effects, and monitoring parameters.
   b. Provide education regarding the importance of Inflammatory Bowel Disease control, adherence to medications, instructions for monitoring and record-keeping.
   c. Discuss potential interfering agents, such as over the counter medications and herbal products.
   d. Discuss lifestyle modifications including:
      a. Diet
      b. Weight Management
      c. Physical Activity
      d. Limiting Alcohol
      e. Smoking Cessation.
6. **Internal** referrals for other ancillary services may be requested for assisting in the management of Inflammatory Bowel Disease or for the management of comorbidities as necessary including
   a. Nutrition Consult
   b. Weight Management Consult
   c. Psychological Co-morbities Consult.

- Disease state & therapy plan education & counseling
- Co-morbidity referrals

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CPA Clinic Discharge

D. Clinical Pharmacy Specialist Service Discharge
1. Patients may be discharged from CPS care if:
   a. Patient is at therapeutic goals for two consecutive CPS visits UNLESS upcoming follow up with the referring provider, who will then determine the next follow up with CPS for the purpose of further improvement in therapeutic goals.
   b. Patient requests CPS service discontinuation. The request and reason(s) for discontinuation will be documented in the patient's medical record. Upon discharge, patients will be encouraged to maintain regular follow-up with their provider(s).
   c. Provider requests CPS service discontinuation.
2. Patients may be discharged from the CPS care prior to reaching pre-defined goals if:
   a. The patient refuses follow-up.
   b. The patient refuses to adhere to the CPS's therapeutic recommendations.
   c. The patient fails to show for two consecutive scheduled appointments after a reasonable attempt by the CPS has been made to encourage follow up.
   d. In every case of discharge
   e. The patient will be encouraged to continue follow-up with their established and/or referring provider.
   f. Documentation of discharge clearly indicates that management is being handed back to the referring provider and continued management would require a new referral to the CPS.
3. Documentation and communication of early discharge of a patient from the CPS care will include:
   a. Notification of the established provider and/or the referring provider.
   b. Documentation in the patient medical record.

- Define procedures for service discharge
- Ensure clear & adequate documentation

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Documentation & Communication

E. Documentation
1. All patient encounters and therapy modifications will be documented in the patient's electronic medical record per institution policy and routed to the referring provider and/or physician for review.

F. Communication
1. All communications related to an individual patient, including those between supervising physician, additional providers, and authorized pharmacist, will be clearly documented in the patient's medical record.
2. The authorized pharmacist will adhere to institution policy with regards to completing and forwarding progress notes and/or visit encounters to providers.
3. The authorized pharmacist will adhere to institution policy with regards to EMR messaging maintenance.

- Ensure clear & adequate documentation
- Best practice to limit number of separate encounters associated with one reason

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Goals of CPA Clinic

G. Outcomes and Quality Assurance

1. Outcomes of Inflammatory Bowel Disease management will include, but not be limited to:
    a. Short term targets of Clinical Response to therapy
        i. Defined in CD as decrease of at least 50% in PRO2 (abdominal pain and stool frequency)
        ii. Defined in UC as decrease of at least 50% in PRO2 (rectal bleeding and stool frequency)
    b. Intermediate targets of Clinical Remission and Decrease in biomarkers CRP and fecal calprotectin
        i. Defined in CD as PRO2 (abdominal pain 1 and stool frequency 3) or HBI <5
        ii. Defined in UC as PRO2 (rectal bleeding¼0 and stool frequency¼0) or partial Mayo (1)
        iii. CRP<5
        iv. Fecal Calprotectin level
    c. Long term targets of Endoscopic Healing and return to normalized QoL and absence of disability
    d. Transmural Healing/Histologic Healing
    e. Increased Adherence through Proportion of Days Covered (PDC)
    f. Decrease in corticosteroid utilization over 365 days (about 12 months)
    g. Decrease in Acute care/hospitalizations
    h. Decrease in Product Complaints through administration technique counseling
    i. Improved Turn-around time to drug in patient hand
2. Risk mitigation through peer review will also occur to confirm adherence to the agreement.
3. Results will be presented to the appropriate pharmacy managers, immediately prior to biennial review.

- Outcome measures
- Ultimate goal: discrete field data available through reporting
- Risk mitigation
- Review/renewal term

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Assessment Question #2

Which of the following are important elements of a specialty clinic ACP practice agreement?

A) Defined outcome measures

B) Ensuring clear and adequate documentation procedures

C) Avoid specific/narrow language unless required

D) All of the above

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Answer Question #2

Which of the following are important elements of a specialty clinic ACP practice agreement?

A) Defined outcome measures

B) Ensuring clear and adequate documentation procedures

C) Avoid specific/narrow language unless required

D) All of the above

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IBD CENTER CPA PHARMACIST

Applications in Clinical Practice

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Inflammatory Bowel Disease Guideline Management – STRIDE-II

Short-Term Targets → *Intermediate Targets* → *Long-Term Targets*

Therapy Plan	**Clinical Response**	**Clinical Remission & CRP Resolution**	**Fecal Calprotectin**	**Endoscopic Healing Quality of Life (-) disability**	**Transmural Histologic Healing**
According to phenotype/ behavior/PMH	Clinical Indices reduction in symptom burden	Normalization of bowel habits; Inflammatory biomarker CRP	IBD Inflammatory biomarker	Endoscopic evidence	Theoretical goals

Treatment Targets Not Met

Source: Turner D, et al. International Organization for the Study of IBD. STRIDE-II: An Update on the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) Initiative of the International Organization for the Study of IBD (IOIBD): Determining Therapeutic Goals for Treat-to-Target strategies in IBD. Gastroenterology. 2021 Apr;160(5):1570-1583. doi: 10.1053/j.gastro.2020.12.031. Epub 2021 Feb 19. PMID: 33359090.

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Available QR Code

- The next slides represent a high-level view of the operational workflow developed for the Collaborative Practice ACP
- For the purposes of the framework it is not necessary to view all details
- If you would like greater visibility, feel free to use this code to view

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Organizational Workflow

Patient
Provider
Ambulatory RPh
SPL/Shared Services
BIDMC SP

Patient presents to MD from referral etc

Provider Impression and Plan - send referral to Amb RPh and notify SPL (Plan of Care)

Amb RPh assists as needed with clinical rationale

SPL completed BI and PA

Authorized or Denied

Authorized

SPL Notifies Amb RPh

Schedules TELEHEALTH and performs Initial Counseling and provides pt opportunity for BIDMC SP
SPL financial barriers addressed and documented

Therapy Changed

Denied

SPL Notifies RPh

Denied: Appeal or Change Tx

RPh responds Appeal

Peer to Peer completed or LOMN provided to SPL for ins submission

SPL submits to ins for coverage redetermination

Pt accepts or Denies BIDMC SP

Declines

Accepts

Rx Order signed to BIDMC SP
RPh F/U 10 day to ensure start then set f/u cadence

Rx Order Queued and sent to preferred Pharmacy
RPh F/U 10 day to ensure start then set f/u cadence

Rx Order Received, pt contacted, URAC assessment completed, agreed upon date for delivery

Pt receives therapy and contacts Amb RPh if further assistance needed for injection

Initial visit to establish care in CPA Clinic

- Baseline characteristics
- Capture symptom history
- Capture quality of life & impact of disease burden
- Discuss treatment plan considerations along with rationale
- Identify care gaps

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Follow-up Visit #1 CPA RPh

Follow Up Care Visit 1 Within 4 Weeks Of Start - RPh

Patient
Doing well or issues
Doing Well On Therapy Without Issue
Pt receives therapy and contacts Amb RPh if further assistance needed for injection
Serious or Repeated Issue

Provider
Provider Intervention
Common Issues
Therapy Change

Ambulatory RPh
Followup Visit 1 (w/i 4 weeks of start) to assess medication safety and tolerability
Pharmacist mitigated and chart updated to reflect recommendations
Pharmacist refers to appropriate urgent care and/or sends stat msg to provider for f/u w/ recommendations
Pharmacist tele f/u
Peer to Peer completed or LOMN provided to SPL for ins submission
Pharmacist Documents progress in chart
Authorized

SPL/Shared Services
SPL completed BI and PA
Authorized or Denied
Denied
SPL submits to ins for coverage redetermination

BIDMC SP
Rx Coverage Issue
SPRx Refill
Rx w/o issues

Tight monitoring with ultimate goals of increased remission rates, reduced hospitalizations, improved quality of life, increased productivity.

Presentations of importance:

- Refractory patient
- Formulation transition IV to SC
- Biosimilar-related concerns
- High-touch patients
- Significant care gap history

Source: Al Khoury A., et al. Assessing adherence to objective disease monitoring and outcomes with adalimumab in a real-world IBD cohort. Dig. Liver Dis. 2021;53:980–986. doi: 10.1016/j.dld.2021.02.006.

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Follow-up Visit #2 CPA RPh

Follow Up Care Visit 2 Month 3/4 - RPh

Patient
Provider
Ambulatory RPH
SPL/Shared Services
BIDMC SP

Clinical Response or Issues
Clinical Response and No Issues
Pt receives therapy and contacts Amb RPh if further assistance needed for injection
No Response or Serious Issues
Limited Response or Common issues
Provider Intervention
Therapy Change
Followup Visit 2 (Month 2-3) to assess appropriateness of dose
Pharmacist documents in chart reflecting recommendations
Pharmacist refers to appropriate urgent care and/or sends stat msg to provider for f/u
Pharmacist tele f/u
Peer to Peer completed or LOMN provided to SPL for ins submission
Pharmacist Documents progress in chart
Authorized
SPL completed BI and PA
Authorized or Denied
Denied
SPL submits to ins for coverage redetermination
Rx Coverage Issue
SPRx Refill
Rx w/o Issues

Cadence set to continue tight monitoring based on

- Presentation
- Sx & biomarkers
- Therapy plan
- Patient preferences
- Provider preferences

Source: Brand E.C., et al. Systematic Review and External Validation of Prediction Models Based on Symptoms and Biomarkers for Identifying Endoscopic Activity in Crohn's Disease. Clin. Gastroenterol. Hepatol. 2020;18:1704–1718. doi: 10.1016/j.cgh.2019.12.014.
Dulai P.S., Feagan B.G., Sands B.E., Chen J., Lasch K., Lirio R.A. Prognostic Value of Fecal Calprotectin to Inform Treat-to-Target Monitoring in Ulcerative Colitis. Clin. Gastroenterol. Hepatol. 2023;21:456–466.e457. doi: 10.1016/j.cgh.2022.07.027

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Follow-up Visit #3 Provider

Follow Up Care Visit 3 Month 2/3 - Provider

Patient

Clinical Response/ Remission or Issues

No Response or repeated issues

Limited Response/Remission or Common issues

Clinical Response and No Issues

Pt receives therapy and contacts Amb RPh if further assistance needed for injection

Provider

Followup Visit 3 (Month 3-4) assess medication efficacy/disease response

Provider documents in chart reflecting progress and recommendations

Provider Intervention

Provider Documents progress in chart

Therapy Change

Ambulatory RPh

Pharmacist tele f/u

Peer to Peer completed or LOMN provided to SPL for ins submission

Authorized

SPL/Shared Services

SPL completed BI and PA

Authorized or Denied

Denied

SPL submits to ins for coverage redetermination

Rx Coverage Issue

BIDMC SP

SPRx Refill

Rx w/o Issues

Traditional tight monitoring with Provider-led visit

- Plans are communicated to CPA
- Changes as needed
- Patient outcomes evaluated at provider level

Source: Colombel J.F., D'Haens G., Lee W.J., Petersson J., Panaccione R. Outcomes and Strategies to Support a Treat-to-target Approach in Inflammatory Bowel Disease: A Systematic Review. J. Crohn's Colitis. 2020;14:254–266. doi: 10.1093/ecco-jcc/jjz131. Colombel J.F., Narula N., Peyrin-Biroulet L. Management Strategies to Improve Outcomes of Patients With Inflammatory Bowel Diseases. Gastroenterology. 2017;152:351–361.e355. doi: 10.1053/j.gastro.2016.09.046. .

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Assessment Question #3

Which of the following is NOT an example of how ACPs collaborate efficiently?

A) Decreasing administrative burden

B) Providing patients increased touchpoints to capture progress

C) ACP taking over patient management with ACP visits in place of provider

D) Operationalizing management to identify high risk patients and prioritizing care

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Answer Question #3

Which of the following is NOT an example of how ACPs collaborate efficiently?

A) Decreasing administrative burden

B) Providing patients increased touchpoints to capture progress

C) ACP taking over patient management with ACP visits in place of provider

D) Operationalizing management to identify high risk patients and prioritizing care

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Operationalization of Guidelines

- Discrete fields in IBD CDTM flowsheet
- C Reactive Protein with last date
- Fecal calprotectin with last date
- Appt with M.D./Advanced practitioner last date
- Therapy history
  - Tx
  - Dates
  - Response
- Estimated total 365 day steroid utilization
- IBD related ED/Admit time to follow up

- Utilize workbench reporting to prioritize patients who need care with urgency
- Ensure clinic safety & efficacy in accordance with accepted standards of practice

Source: Dignass A., et al. Review article: Translating STRIDE-II into clinical reality—Opportunities and challenges. Aliment. Pharmacol. Ther. 2023;58:492–502. doi: 10.1111/apt.17622.

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Operationalization of Guidelines, cont'd.

Report Settings - Lahey IBD Center Outcomes Data - Weekly [14206147]

Criteria | Display | Appearance | Summary | Print Layout | Toolbar | Override | General

Find Patients

Find Criteria: Enter a search term, or click the search icon to browse available criteria

Date Range From: M-1 To: T

Run as user

- PELLISH, RANDALL OR
- FARWELL, KRISTEN E OR
- GREGG, GAIL M OR
- SPIEWAK, JEREMY OR
- WARNER, ANDREW S OR
- DANIS, JACQUI

Diagnosis by grouper

- EDG CONCEPT HX INFLAMMATORY BOWEL DISEASE OR
- EDG CONCEPT HX CROHNS DISEASE OR
- EDG CONCEPT HX ULCERATIVE COLITIS

Encounter department

- BUR GASTROENTEROLOGY OR
- BH 50 MALL RD GI MGMT OR
- BVH BEDFORD GI MGMT

Visit: Type

- Office Visit OR
- Initial consult OR

Report Logic AND

Show search summary

Run | Save | Save As | Restore | Close

Report Settings - Lahey IBD Center Outcomes Data - Weekly [14206147]

Criteria | Display | Appearance | Summary | Print Layout | Toolbar | Override | General

Available Columns

Search available columns

- (Retired) CHADS2 Score [4702]
- (Retired) Patient Audit Trail [17090]
- Active End Date [14123]
- Active Questionnaire Series [15260]
- Active Start Date [14122]
- ASCVD 10-Year Risk Score [4708]
- Can Receive Patient Portal Message [32010]
- CVD 10-Year Risk Score [4029]
- Diabetes Composite Score [4701]

Add

Selected Columns

- Patient Sex [54501]
- ED Visit Count - Past 90 Days [4450]
- ED Arrival Date/Time [49530]
- Hospitalizations - Past 90 Days [4452]
- AMB Last Encounter This Provider [103614]
- AMB NEXT APPT WITH ME [210220172]
- AMB LAST APPT WITH ME [210220171]
- Next Encounter This Department [17161]
- Last Encounter This Department [17163]
- Encounter Type (EPT) [450]

Anchor: 0 Columns

Detailed Views

Detailed View	Display Name

Run | Save | Save As | Restore | Close

Source: Beth Israel Lahey Health data. Not for reuse without permission of Beth Israel Lahey Health

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Operationalization of Guidelines, *contd.*

IBD Synopsis		Epic Code
<<<VITALS>>>		
Height		
Weight		
BMI		
<<<LABS>>>		
Inflammatory Markers		
C-Reactive Protein		[LAB149]
Calprotectin Stool		[LAB3610]
Lactoferrin Stool		[LAB731]
Sed Rate		[LAB322]
Complete Blood Counts		
WBC		[LAB299]
Hemoglobin		[LAB291]
Hematocrit		[LAB289]
Platelet Count		[LAB301]
Liver Function Tests		
Alk Phos		[LAB112]
AST		[LAB131]
ALT		[LAB132]
Albumin		[LAB45]
GGT		[LAB85]
Bilirubin		[LAB52]; [LAB50]
Iron Studies		
Ferritin		[LAB68]
Iron Level		[LAB94]
Total Iron Binding Capacity		[LAB829]
Nutrient Studies		
Vitamin B-12 Level		[LAB67]
Vitamin D total		[LAB536]
25 OH-vitamin D		[LAB3043]
Hepatitis Serologies		
Hepatitis B Surface Antigen		[LAB471]
Hepatitis B Surface Antibodies		[LAB472]
Hepatitis B Core AB		[LAB2628]
Misc. Labs		

<<<IBD Therapies>>>	
Biologics/Small Molecules	
Adalimumab	
Initial Start Date	1/1/2024
End Date	4/20/2024
Reason Discontinuation	Immunogenicity
Certolizumab	
Initial Start Date	
End Date	
Reason Discontinuation	
Golimuimab	
Initial Start Date	
End Date	
Reason Discontinuation	
Infliximab	
Initial Start Date	
End Date	
Reason Discontinuation	
Ozanimod	
Initial Start Date	
End Date	
Reason Discontinuation	
Rizankizumab	
Initial Start Date	

Dropdown options: Mechanistic Failure; Secondary LOR; ADEs; Side Effects; Insurance/Financial Barrier; Immunogenicity; Z-Other

Source: Beth Israel Lahey Health data. Not for reuse without permission of Beth Israel Lahey Health

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CPA Clinic Stats

CPA Intervention Estimates	Stat
Initial therapy plan approvals	160
Prescribing by RPh	73
LOMNs generated with approved vs. denied	159 vs.10
Peer-to-peer approved vs. denied	32 vs. 2
PAP/financial barriers addressed	35
Unique patients seen vs. follow up	200 vs. 126
Administration counseling provided	180
Inpatient salvage therapy initiation support	5
Pharmacist-led Interventions	22

Commonly Referenced ACP Interventions

Sources: Bhat S, Zahorian T, Robert R, Farraye FA.. Advocating for patients with inflammatory bowel disease: how to navigate the prior authorization process. Inflamm Bowel Dis. 2019;25(10):1621–1628.
Bhat S. Optimizing Medication Access and Use in Inflammatory Bowel Disease: The Roles and Impact of Clinical Pharmacists and Pharmacy Technicians. Crohns Colitis 360. 2023 Mar 9;5(2):otad014. doi: 10.1093/crocol/otad014. PMID: 36937137; PMCID: PMC10022714.
Choi DK, et al. Delays in Therapy Associated With Current Prior Authorization Process for the Treatment of Inflammatory Bowel Disease. Inflamm Bowel Dis. 2023 Oct 3;29(10):1658-1661. doi: 10.1093/ibd/izad012. PMID: 36715294.
Choi DK, Puangampai A, Rubin DT. Prior Authorization for Ustekinumab Dose Escalation Negatively Affects Outcomes in Patients With Inflammatory Bowel Disease. Ann Pharmacother. 2022 Mar 18:10600280221080986. doi: 10.1177/10600280221080986. Epub ahead of print. PMID: 35300521.
Choi DK, et al. Role and Impact of a Clinical Pharmacy Team at an Inflammatory Bowel Disease Center. Crohns Colitis 360. 2023 Apr 15;5(2):otad018. doi: 10.1093/crocol/otad018. PMID: 37082614; PMCID: PMC10111283.

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Case Example #1

Patient ABC

40 yo female. Pan-colonic, fistulizing Crohn's disease, initial UC dx about a decade ago

IBD COMPLICATIONS:
- Iritis/Uveitis
- C diff
- Colovaginal fistula
- UTI c/p pyelonephritis

IBD MEDICATIONS:
- Steroids, 5-ASA enema, 5-ASA MMX, 6-MP, ADA, VDZ, UST, combo AZA, TOF, IFX, VDZ, combo MTX, ADA/VDZ

- Pt presents to PTM Clinic for evaluation and therapy plan recommendations
- Considerations given to ADA previous mucosal response, along with immunogenicity concerns with IFX and multiple ADA trials, CZP v GOL dual off label indications
- Initiated pt on therapy 2023
- COLO 2024 improved compared to previous outside examinations.
- Pt able d/c steroid drop (did need IOP tx momentarily) Uveitis resolved
- Fistula drainage/gas was resolved

* * *

- CPA Interventions: RPh PA turnaround 24 hr approved 1st round; Med access copay assistance; white glove; admin training; follow up; change of ins PA denial; LOMN appeal approved

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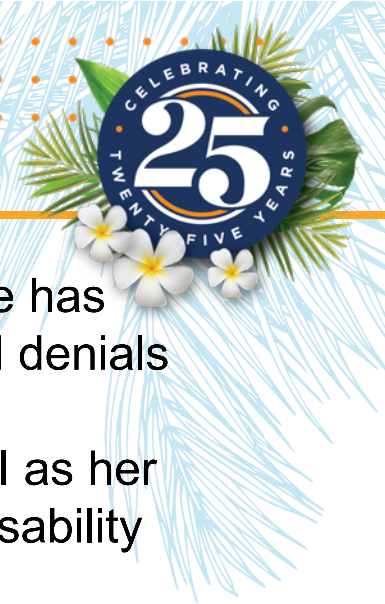
Case Example #2



Patient DEF

60 yo female. Colonic, perianal fistulizing Crohn's disease, (initial UC dx decades ago)

IBD COMPLICATIONS:
- Colovaginal fistula
- anal SCC w/XRT +chemotx in remission
- Steroid associated AVN

IBD MEDICATIONS:
- Steroids, AZA, MTX, IFX, ADA< CZP, dose-escalated ADA

- Pt presents to PTM Clinic for evaluation and support as she has experienced a 5-week delay in ADA tx d/t insurance related denials of both PA and appeals for continued treatment plan.
- Clearly documented in chart impact on quality of life as well as her clinical response to therapy and how it has impacted her disability level.
- Biosimilar ADA-adaz transition with immediate concerns voiced by patient.
  - Provided additional clinic visits to discuss transition and provide level of detail for the patient to understand what biosimilar is
  - Provided visits as follow up to monitor patient reported outcomes

* * *

- CPA Interventions: RPh PA denied; Using detailed support regarding QoL from PTM clinic visit along with interval history; LOMN appeal approved; Biosimilar transition consultation and baseline evaluation; ADA-adaz signs of failure (PROs) and pursuit of PA RLD ADA, denied, and then with detailed support and LOMN, appealed successfully..

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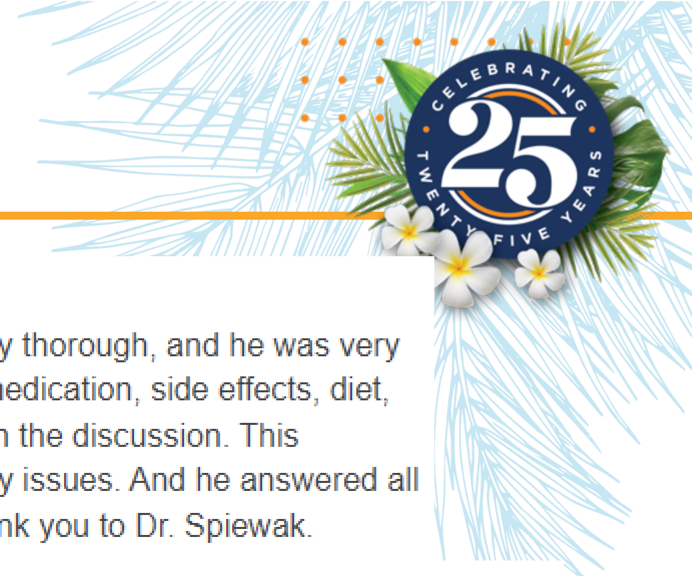
CPA Clinic Patient Approval Rating



Pt Feedback Report

Total Visit Count 326

123 Reviews

Comments:

My appointment with Dr. Spiewak was very thorough, and he was very clear on each thing discussed. Process, medication, side effects, diet, insurance, and next steps were included in the discussion. This appointment gave me clarification on many issues. And he answered all the questions I have at this time. A big thank you to Dr. Spiewak.

Comments:

I felt like he really cared and wasn't just passing me through my appointment. He was giving legitimate thought to my concerns and trying to understand patterns in my symptoms. He was really listening to me and taking my questions/thoughts seriously. And he was very well informed and I appreciated the effort he took to thoroughly explain my medication to me.

Comments:

This call was SO informative. All of my questions were answered and my fears of moving to a new medication were allayed. I feel incredibly supported by having Dr. Spiewak as part of my care team and I know that my ongoing needs will be addressed with him as a partner to my care team. I learned a lot today and I feel confident that my care is in good hands. Thank you!!

Source: Beth Israel Lahey Health data. Not for reuse without permission of Beth Israel Lahey Health

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“Make you better, keep you better.”

~ **Randall Pellish**, M.D.
Chief of the Division Gastroenterology, LHMC
Director of Lahey Inflammatory Bowel Center
Associate Professor of Medicine
Tufts University

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Thank you…

Jeremy KW Spiewak, PharmD, MCSR-RPh, MSCS
jeremy.spiewak@lahey.org

Beth Israel Lahey Health
Lahey Inflammatory Bowel Disease Center
Massachusetts

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