
5-ASA 400
MESALAZINA
PENTASA®
Mesalazina 2g
Granulado de Liberación prolongada
Remicade
(Infliximab)
For Injection
100 mg per vial
Each patient is required to receive the enclosed Medication Guide
ASACOL
ASACOL
CinnoRA
Pentasa®
SLOW RELEASE TABLETS
500 mg
Entocort®
budesonidum
Imuran
PREDNISON 20 LEČIVA
Nature Made
Folic Acid
TORENZO®
Ozanimod
Tofacitinib
Tablets 5 mg
Tacotinib 5
10 x 10 Tablets
Prednisolon 5 mg
30 tablets
Calcium and
Vitamin D3 Tabl
CIPCAL-500

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Treatment monitoring in IBD

Introduction

- Inflammatory Bowel Disease (IBD), which includes Crohn's disease (CD) and ulcerative colitis (UC), is a chronic, progressive condition that can lead to irreversible complications if not treated effectively.
- Traditional treatment focused on symptom relief, but
  - Symptoms do not always correlate with disease activity
- Modern approaches aim for
  - Objective markers of inflammation
  - Emphasizing mucosal healing
  - Long-term remission

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Treatment monitoring for IBD

- Here's an overview of current guideline-based approaches, largely based on ECCO (European Crohn's and Colitis Organization) and AGA (American Gastroenterological Association) recommendations



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Importance of Disease Monitoring

- **Effective monitoring helps:**
  - Assess treatment response
  - Adjust therapies proactively before complications arise
  - Reduce hospitalizations and improve quality of life
- **IBD is highly variable:**
  - Some patients have mild disease, while others have
  - Aggressive
  - Treatment-resistant disease
- **The STRIDE-II guidelines define time-dependent treatment goals to improve long-term outcomes.**

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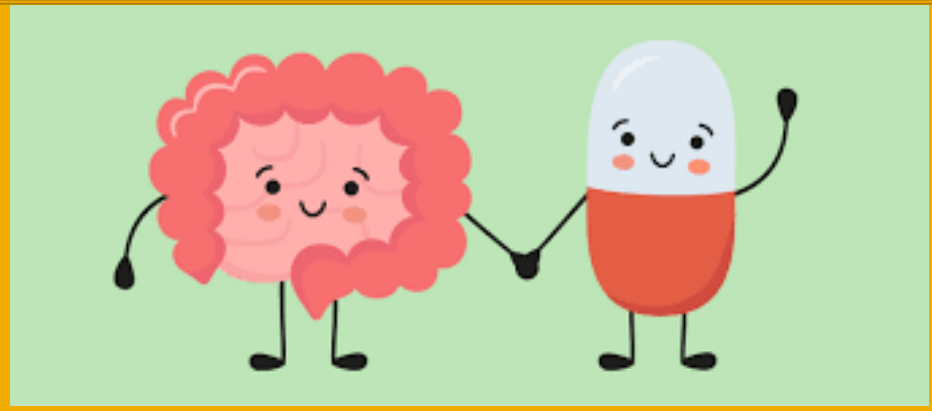
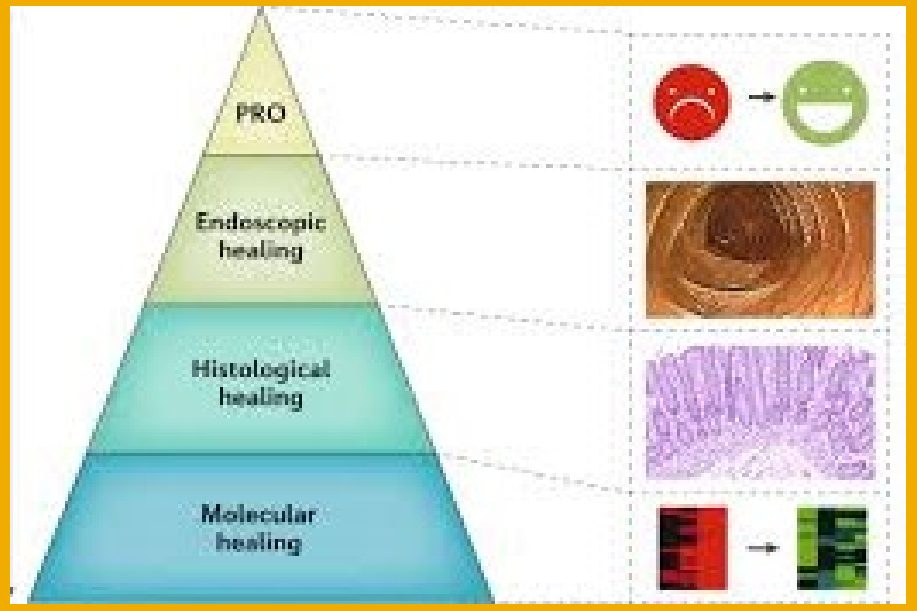
Goals of Monitoring

Achieve and maintain clinical remission



Achieve endoscopic healing

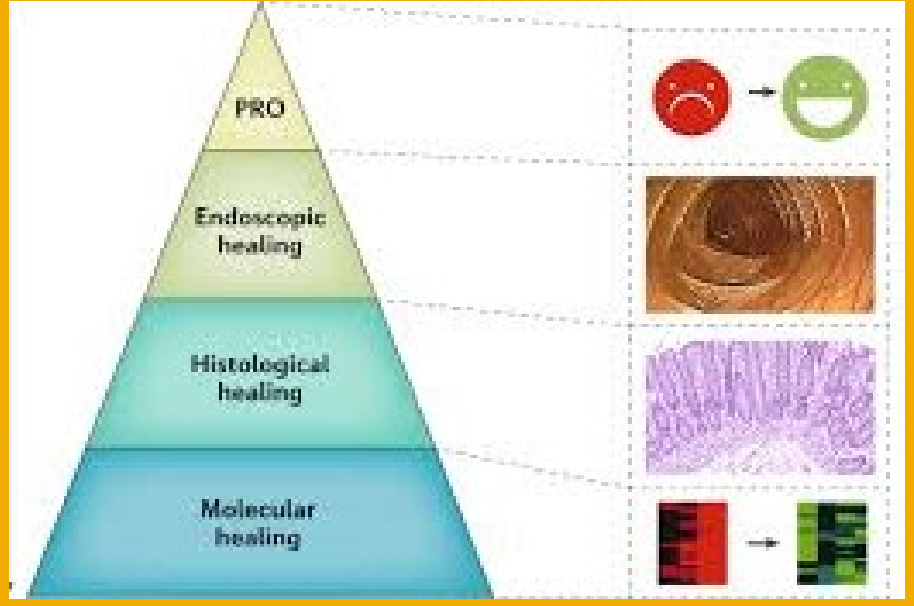


Prevent





Achieve endoscopic healing



Prevent hospitalizations and surgeries





Minimize medication side effects



surgeries





Minimize medication side effects



Improve quality of life



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Clinical Symptoms & Patient-Reported Outcomes (PROs)

- Historically, symptoms (pain, diarrhea, weight loss) were used
  - Assess IBD activity
- However, symptoms correlate poorly with actual inflammation
  - especially in Crohn's disease
- PROs (Patient-Reported Outcomes):
  - Tools like the PRO-2 score help assess quality of life (QOL) but
  - Cannot replace objective disease markers

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🔬 Serum Biomarkers

- 🔬 C-reactive protein (CRP):
  - A widely used, cost-effective marker of inflammation
  - Shortcomings:
    - Not specific to IBD (can rise due to infections, other inflammations)
    - Low sensitivity (some IBD patients do not show CRP elevation)

- CRP is useful but not sufficient as a standalone marker

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🔬 Fecal Biomarkers

- 🔬 **Fecal Calprotectin (FC):**
  - A non-invasive, highly accurate stool test for detecting intestinal inflammation
  - Superior to CRP in predicting mucosal inflammation
  - Used in tight control strategies (e.g., CALM trial), where regular FC testing helped adjust therapy before symptoms appeared
  - Threshold for concern:
    - >250 mg/g suggests active inflammation
    - Post-operative CD: >100 mg/g can indicate disease recurrence

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Imaging

- **Magnetic Resonance Imaging (MRI) & Magnetic Resonance Enterography (MRE):**
  - Key tool for Crohn's disease to detect deep inflammation and strictures
  - Challenges: Expensive, requires radiologists, long waiting times
- **Intestinal Ultrasound (IUS):**
  - A rising, real-time imaging technique
  - Benefits: Non-invasive, fast, no radiation
  - Limitations: Requires expertise, limited small-bowel reach

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Endoscopy

- **Ileo-colonoscopy:**
  - Gold standard for mucosal healing assessment
  - Helps identify ulcers, strictures, and complications
  - Limitations: Invasive, expensive, requires bowel prep and sedation

- **Capsule Endoscopy (CE):**
  - Can visualize small bowel inflammation in Crohn's disease
  - Risks: Capsule retention, high cost, limited availability

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Optimal Monitoring Strategy (Treat-to-Target Approach)

A. Baseline Assessment

- A comprehensive assessment should be performed at diagnosis, including:
  - Clinical symptoms (Harvey-Bradshaw Index, Mayo Score)
  - Blood tests (CRP, albumin, hemoglobin)
  - Stool tests (FC)
  - Endoscopic & imaging assessment

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Optimal Monitoring Strategy (Treat-to-Target Approach)

- **Regular Disease Monitoring ("Turbo T2T")**
  - Frequent FC testing (every 2-3 months) to detect early inflammation before symptom relapse
  - Periodic imaging and endoscopy (every 12 months or as needed) to confirm deep remission
  - Therapeutic Drug Monitoring (TDM) to optimize biologic therapy

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Key Aspects of Monitoring

- Clinical Assessment

- • Symptom scoring tools:
  - Crohn's Disease:
    - Harvey-Bradshaw Index (HBI)
    - Crohn's Disease Activity Index (CDAI)
  - Ulcerative Colitis:
    - Partial Mayo Score

- • Frequency:
  - Every 3–6 months, or more often if active disease

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Monitoring Timeline

- After initiating or changing therapy:
  - Clinical symptoms: Assess within 2–8 weeks
  - CRP and Fecal Calprotectin: 4–12 weeks
  - Endoscopy:
    - UC: 3–6 months if moderate-severe disease
    - Crohn's: 6–12 months (or sooner if non-responsive)

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Monitoring Timeline

- **Stable Patients (Maintenance Phase):**
  - Clinical assessment: Every 3–6 months
  - CRP & Fecal Calprotectin: Every 3–6 months
  - Endoscopy: Every 1–2 years, especially in high-risk patients

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Monitoring Timeline

- **Post-surgical (Crohn's):**
  - **Endoscopic check (Rutgeerts score) at 6 months**

- **Scoring Criteria**
- The Rutgeerts score ranges from **R0 to R4**:
  - **R0**: No signs of recurrence (normal mucosa)
  - **R1**: Minor lesions; <5 aphthous ulcers
  - **R2**: Moderate lesions; >5 aphthous ulcers or ulcers with a diameter <1 cm
  - **R3**: Severe lesions; ulcers >1 cm in diameter that do not cause strictures
  - **R4**: Very severe lesions; presence of strictures or fistulas

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Therapeutic Drug Monitoring (TDM)

💊 Therapeutic Drug Monitoring (TDM)

- Especially important for anti-TNF therapy (like infliximab, adalimumab)
- Two strategies:
  - Reactive (after response loss)
  - Proactive (preemptive dosing)
- Reactive TDM:
  - In case of loss of response
- Proactive TDM:
  - Some guidelines support this to maintain optimal drug levels

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Dose Recommendations & Target Trough Levels

- **Infliximab:**
  - Clinical Remission >5 µg/mL
  - **Maintain** levels >5-7 µg/ml for clinical remission
  - Endoscopic Healing 7-10 µg/mL
  - Aim for >10 µg/ml for mucosal healing



Dose Recommendations & Target Trough Levels

- **Adalimumab:**
  - **Maintain** levels >10-12 µg/ml for both clinical and endoscopic remission
  - CD ≥5 µg/mL, UC ≥6.4 µg/mL
  - Healing: >10-12 µg/mL



Dose Recommendations & Target Trough Levels



- **Ustekinumab:**
  - Measure levels at week 8
  - Aim for levels >1.5-3 µg/ml for clinical remission
  - >4.5 µg/ml for endoscopic response
  - Week 8:
    - Clinical ~3.9
    - Endoscopic >11.1 µg/mL

Dose Recommendations & Target Trough Levels

- **Vedolizumab:**
  - **Currently, there isn't enough evidence for routine therapeutic monitoring during maintenance**
  - **Week 2 >30, Week 6 >24, Week 14 >14 µg/mL**
  - **UC/CD:** Trough levels of about **20 µg/mL** are often suggested, especially during maintenance therapy



Antibody Monitoring (ADAs)

- ADAs can reduce
  - Drug efficacy
- Drug-tolerant vs. drug-sensitive techniques
- Persistent high ADAs are clinically relevant

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Clinical Recommendations

- Measure drug levels during
  - Induction
  - Maintenance
- TDM essential after
  - Dose reduction or
  - Before withdrawal
- Use consistent testing methods/labs

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Clinical Recommendations

- **When to Escalate Treatment**
  - • Persistent symptoms
  - • Elevated biomarkers (CRP, Calprotectin)
  - • Incomplete mucosal healing on endoscopy
  - • Active disease on imaging

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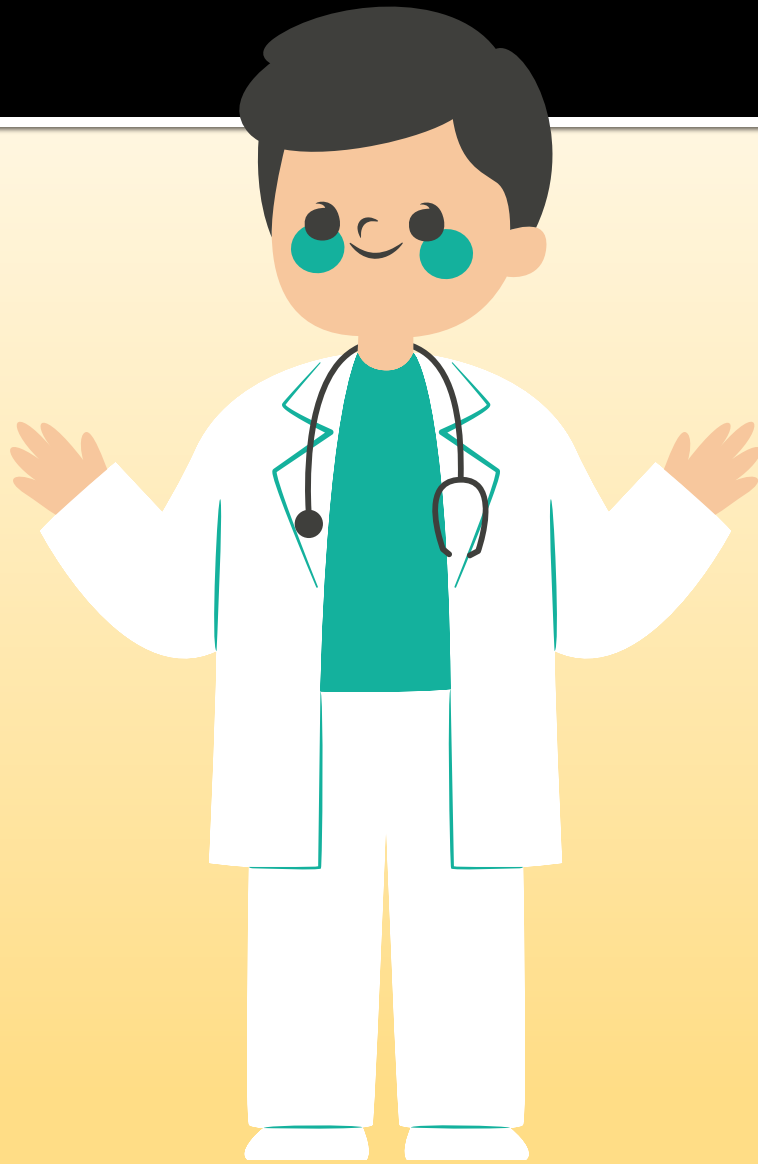
Special Considerations

- **Pediatric patients:**
  - Include growth and nutritional assessment
- **Pregnancy:**
  - Adjust safe medications and increase monitoring
- **Extra-intestinal manifestations:**
  - Monitor joints, skin, eyes
- **Mental health and quality of life:**
  - Routine psychosocial evaluation



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Future of IBD Monitoring



Technological advancements are transforming IBD monitoring

Remote Monitoring & Wearable Devices

- **Point-of-Care (POC) Testing:**
  - Patients can measure CRP and FC at home and send results via mobile apps
- **Wearable Devices (Fitbit, Smartwatches):**
  - Can track heart rate, sleep, physical activity, which correlate with disease flares
  - Early studies suggest step count and sleep patterns may predict flare-ups

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Future of IBD Monitoring



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Monitoring Strategy: "Treat to Target"

Adopted from the **STRIDE guidelines** (Selecting Therapeutic Targets in IBD):

Parameter	Target
Clinical Symptoms	Resolution of diarrhea, bleeding, pain
Biomarkers	Normal CRP, Fecal calprotectin <150–250 µg/g
Endoscopy	Mucosal healing (no ulcers or erosions)
Imaging	No active inflammation on MRI/CTE/US
Histology (optional)	No neutrophilic infiltrate (in UC)

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STRIDE-II

S: *Sustained Remission*
T: *Tolerable Symptoms*
R: *Retention of Steroid-free and Immunomodulator-free Remission*
I: *Inflammation Control*
D: *Disease Prevention*
E: *Education and Empowerment*
I: *Individualization*

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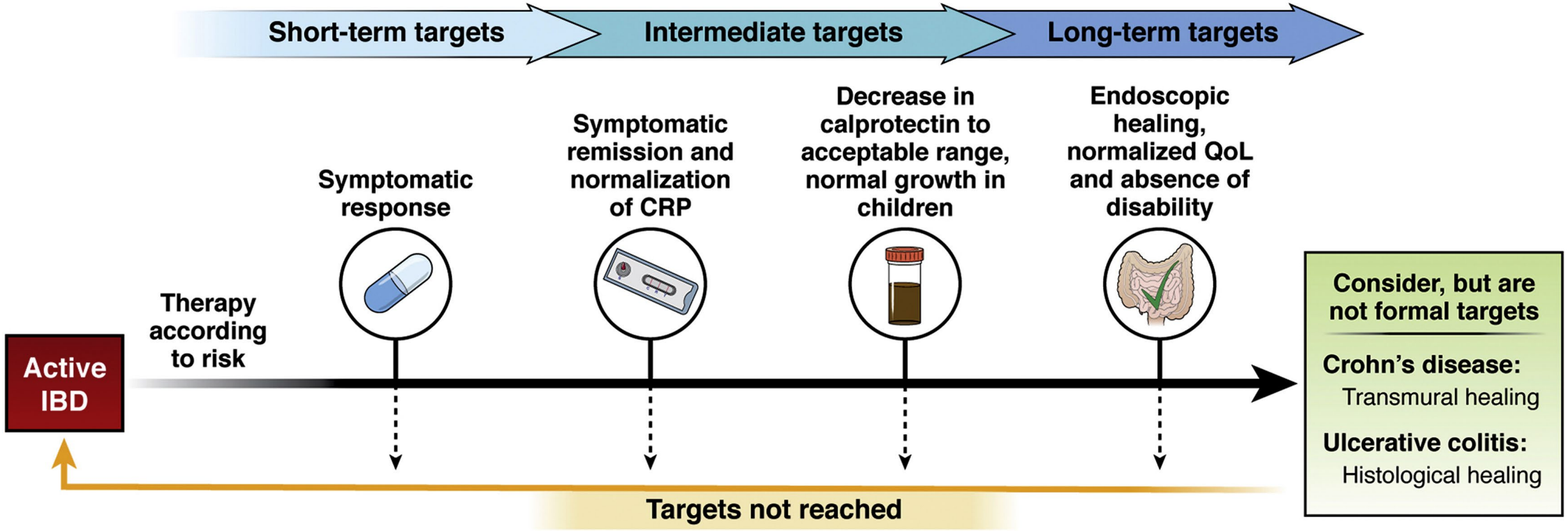
Treatment targets in Crohn's disease and ulcerative colitis per STRIDE-II recommendations



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TREATMENT MONITORING IN

(CROHN'S DISEASE and ULCERATIVE COLITIS)

GOALS OF TREATMENT MONITORING

- Achieve and maintain clinical remission
- Prevent complications and hospitalizations
- Promote mucosal healing (endoscopic remission)
- Monitor for drug toxicity and side effects

KEY ASPECTS OF MONITORING

A. CLINICAL ASSESSMENT

Symptom scoring tools:

- Harvey Bradshaw Index (HBI) Crohn's Disease Activity Index (CDAI): Partial Mayo Score

Frequency: 3–6 months, or more often if active

B. LABORATORY TESTS

Inflammatory markers:

- C-reactive protein (CRP)
- Erythrocyte sedimentation rate (ESR)
- Fecal calprotectin (ncon-invasive marker of Intextinal infl:ammation)
- Blood counts, liver and kidney function tests, especially if on immunosuppressants

D. ENDOSCOPY

- Colonoscopy or sigmoldoscopy to assess mucosal
- Typically done at 6-12 months after starting therapy or based on symptoms
- Surveillance for dysplasia in long-standing IBD

E. THERAPEUTIC DRUG MONITORING (TDM)

- For biologics (infliximab, adaiimuj) Measuring drug levels and anti-drug antibodes **Helps**-guide-dose adjustment or switch in therapy
- Reactive vs proactive Tm: onse (more deoated. Or-debated)

FREQUENCY OF MONITORING

Disease Activity	Monitorring Frequency
Active Disease	Every 1–3 months
Remission	Every 3–6 months (Lab markers), 6–12 months
After Therapy Start/Change	2–6 weeks (lab markers), 6–12 months

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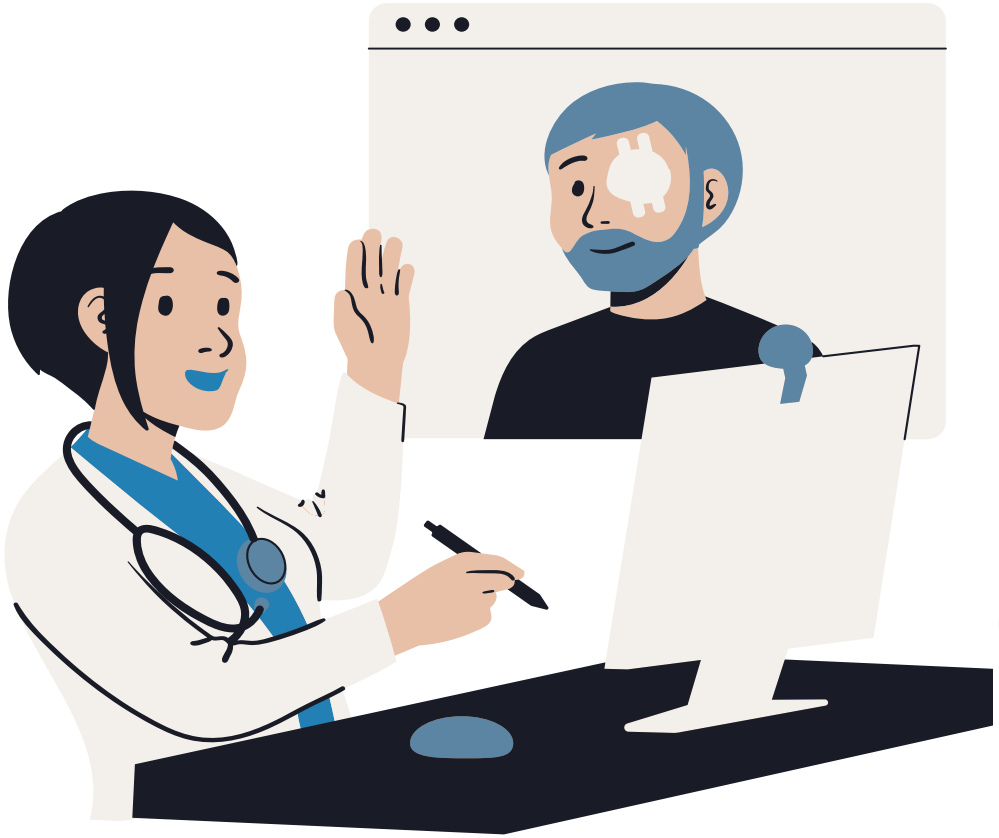
Thanks for Your Attention



Questions or comments?



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