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Early Adoption of New Combination Biologic Therapy Enabled by Enhanced Diagnostic Accuracy in Inflammatory Bowel Disease (IBD) can be a budget neutral approach - A budget impact analysis in Italy

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OBJECTIVE

Despite the therapeutic innovation in new biologic treatments for Crohn's Disease (CD) and Ulcerative Colitis (UC), real-world response rates remain capped at ~40% ("efficacy ceiling"), regardless of treatment mechanism or line of therapy [1]. Evidence suggests that combination therapy using biologics with complementary mechanisms of action may increase response up to 60% [1]. However, access to such combinations is typically restricted to patients who have failed at least two previous biologic lines, largely due to pharmaceutical cost considerations.
This study aims to estimate the budget impact of integrating novel diagnostic non-invasive technologies and to evaluate their potential to offset drug acquisition costs and expand early access to combination therapy under cost-neutral conditions.

METHODS

A 5-year budget impact model was developed from the perspective of the Italian National Health Service. Two connected modules were implemented:

1. **Diagnostic model** to quantify the ability to defer invasive diagnostic methodologies (e.g., colonoscopies) and downstream costs due to improved novel non-invasive diagnostic test specificity;
2. **Budget impact model** to assess the reinvestment potential of these savings into earlier use of combination biologics in first- and second-line settings, without increasing overall expenditure.

Diagnostic model

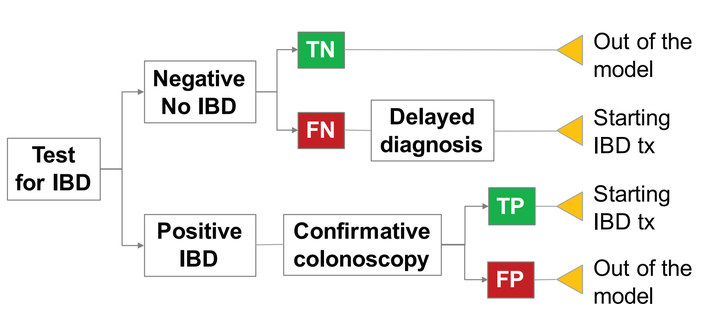
- A decision tree was developed to simulate the IBD diagnostic pathway of Italian patients presenting with chronic abdominal pain (Figure 1). The standard Calprotectin (Calpro) test was compared with a novel non-invasive diagnostic test in development.
- Sensitivity and specificity for each test, as well as IBD prevalence, were derived from investigational data [2].
- Among negative results, true-negative (TN) patients exit from the model without further investigation while false-negative (FN) patients are assumed to start treatment for IBD after spending a period unsuccessfully treated for irritable bowel syndrome (IBS) [3].
- All positive results undergo a confirmative colonoscopy (100% accuracy assumed) and then true-positive (TP) patients start treatment for IBD while false-positive (FP) patients exit from the model. Adverse events post colonoscopy were also included in the evaluation [4]
- Unit costs are estimated based on Italian reimbursement tariffs or published literature [5,6]. Finally, the cost of non-invasive diagnostic tests is assumed equal [5].

Budget impact model

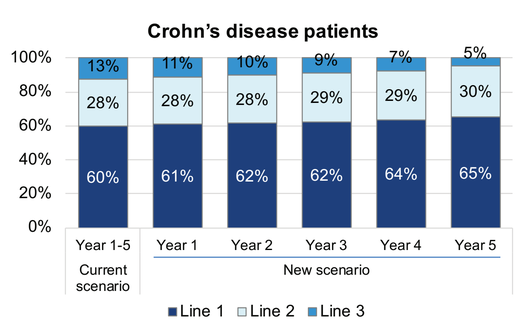
- CD and UC patients treated with biologic drugs (any line) were estimated based on Italian epidemiology [7,8]. Two scenarios have been compared in the analysis:
  - In the **Current scenario**, the standard treatment pathways for IBD patients was simulated [1]: anti-tumor necrosis factor (anti-TNF) monotherapy or tofacitinib (only for UC) in first biologic line; monotherapy with monoclonal antibody (mAB) in second line.
  - In the **New scenario**, early access to combination therapy was simulated: anti-TNF + mAB in first line, anti-TNF + mAB, 2 mABs, tofacitinib + anti-TNF or mAB (for UC only) in second line.

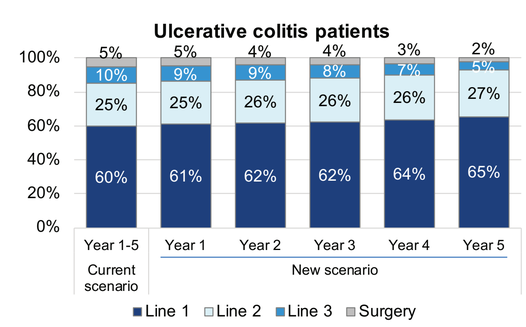
  Third line (in both scenarios), was assumed equal to second line of the New scenario.
- The annual distribution of patients among lines of therapy was assumed constant throughout the time horizon in the Current scenario (Figure 2).
- In the New scenario it was assumed that the increment of efficacy due to the early use of combination therapy in the first two lines of treatment (from 40% to 60% [1]), produces an increase of about 80% of the time spent in these two lines (time spent on treatment was estimated by assuming an exponential distribution). Such effect is applied only to treatment-naïve patients that represent ~20% of total patients in treatment [7] (Figure 2).
- Cost included in the analysis are drug acquisition, administration, and cost of surgery. For CD patients, surgery is assumed to be an event occurring in any line of treatment (6.76% in line 1, 13.06% in line 2, and 18.94% in line 3 [9]) while for UC patients, surgery is modelled as a subsequent health state after the third line of treatment.

Figure 1. Decision tree simulating the diagnostic pathway with Calpro or novel non-invasive diagnostic test and input parameter used to feed the model



Clinical input	Value
IBD prevalence	9.73%
% AE after colonoscopy	0.44%
Time delayed diagnosis	148 days
Economic input	**Value**
Non-invasive diagnostic test	€ 15.95
Colonoscopy	€ 154.90
AE management	€ 4,160.81
Annual IBS treatment	€ 1,036.59





RESULTS

- Results of the **Diagnostic model** highlighted a potential saving associated with the novel non-invasive diagnostic test of € 38.96 for tested patient, due to less unnecessary colonoscopies, mainly. Based on the prevalence of IBD diagnosis [2], each diagnosed patient was associated with a savings of € 400.46 (Table 1).
- Over the total Italian population, improved specificity, due to novel diagnostic non-invasive technologies implementation, while assessing for IBD first diagnosis, leads to deferred colonoscopies, generating annual savings of approximately €20 million.
- Full reinvestment of these savings into pharmacological budgets dedicated to first- and second-line biologic treatments would support progressive adoption of combination therapy, reaching 50% of biologic-treated patients by year five (Figure 3).
- According to this uptake of early access in the New scenario of the **Budget impact model**, over a 5-year time horizon the increasing in the cost of drugs (+103 M€) would be completely offset by the savings in surgery costs (-3.4 M€) and in diagnostic costs (-99.6 M€) (Figure 4).
- The shift would enable improved response, earlier combination use, improved remission, and reduced surgical interventions over the analysis period.

Table 1. Total cost per tested and diagnosed patient with and without novel diagnostic non-invasive technologies

Cost drivers	Calpro	Novel diagnostic test	Delta
Diagnostic test	€ 15.95	€ 15.95	€ 0.00
Colonoscopy	€ 65.31	€ 28.47	-€ 36.84
AE management	€ 7.79	€ 3.40	-€ 4.39
Misdiagnosed IBS treatment	€ 6.81	€ 9.08	€ 2.27
Total per tested patient	**€ 95.86**	**€ 56.90**	**-€ 38.96**
Total per IBD diagnosed patient	**€ 985.20**	**€ 584.74**	**-€ 400.46**

Figure 3. Early access to combination therapy potentially financed

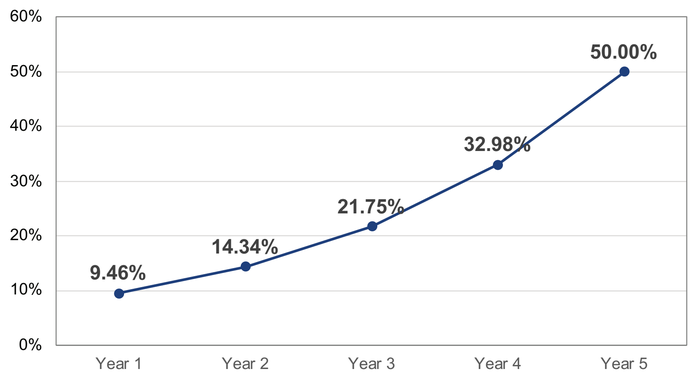


Figure 4. 5-year budget impact results

CONCLUSIONS

Innovative non-invasive diagnostic technologies can unlock substantial economic value by optimizing the IBD diagnostic pathway. Reinvesting these savings into early combination biologic therapy could improve clinical outcomes while maintaining budget neutrality, supporting a more effective and sustainable management strategy for one IBD patient over two by year five.

REFERENCES

1. Ahmed W et al. Clin Gastroenterol Hepatol. 2022;20(3):e361-e379 10.1016/j.cgh.2021.03.034
2. DiaSorin data on file
3. Ministry of Health – Definizione delle tariffe dell'assistenza specialistica ambulatoriale e protesica. DM November 25, 2024
4. Benazzato L et al. Endoscopy. 2021 May;53(5):501-508. 10.1055/a-1228-9225
5. Holmes H et al. Expert Rev Pharmacoecon Outcomes Res. 2022:22(3):521-528 10.1080/14737167.2020.1751613
6. Tack J et al. BMC Gastroenterology. 2019;19:69 10.1186/s12876-019-0985-1
7. Crocetti E et al. Eur J Gastroenterol Hepat. 2021;33(1S):e383-e389 10.1097/MEG.0000000000002107
8. Dovizio M et al. Adv Ther. 2024;41(6):2282-2298 10.1007/s12325-024-02840-x
9. Spoor W. Hospital Episode Statistics (HES) admitted patient care data set 2011-2014.

ISPOR Europe - Glasgow 2025

Acknowledgements This analysis was funded by DiaSorin SpA, Italy