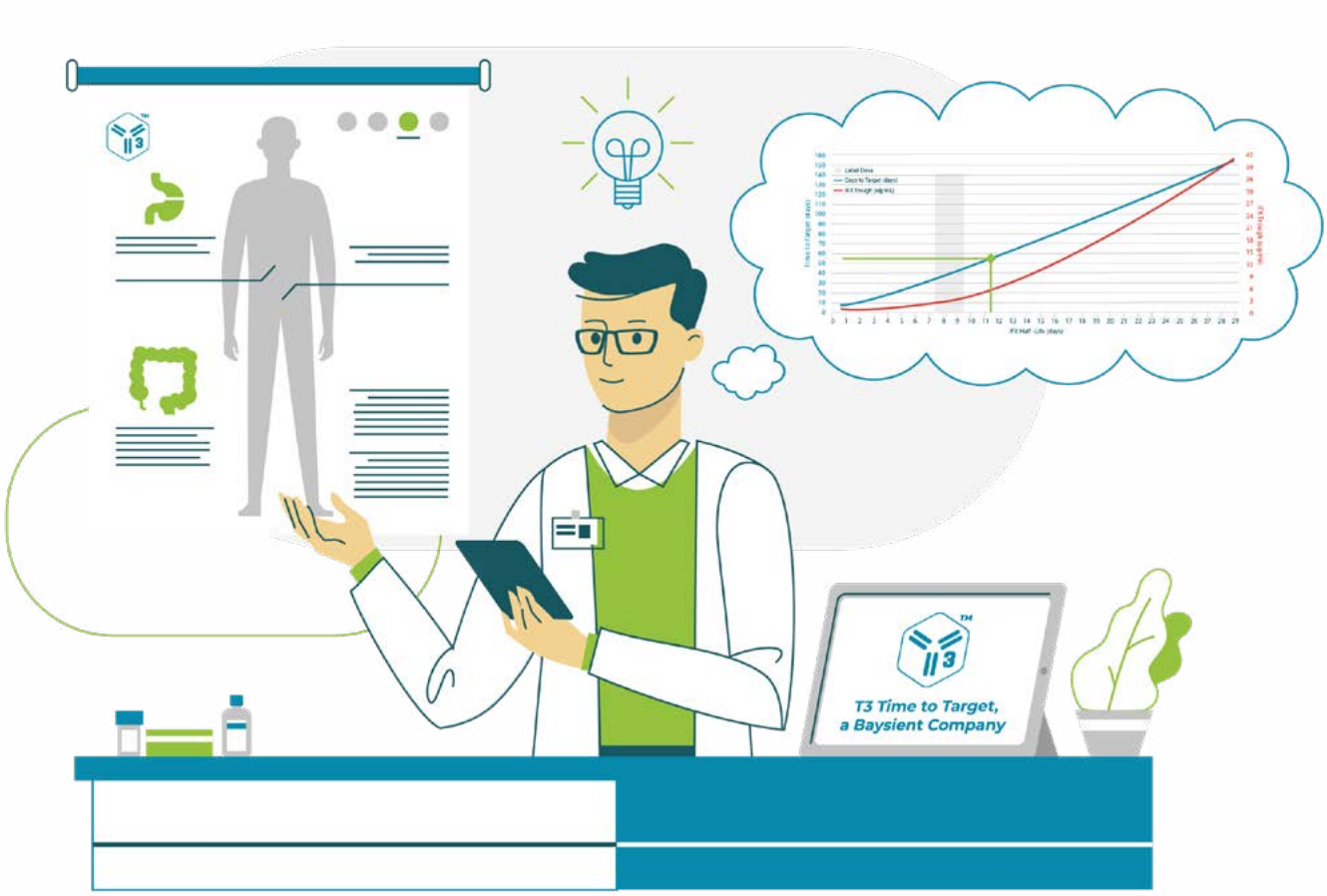
Reimbursement Guide

Built to reduce the uncertainty of dosing decisions, Baysient developed cloud-based software that provides physicians with a full line of individual-dosage-evaluation products.

Physicians can use T3 and iDose to peruse precise dosing information, including how much and how often to provide infliximab (IFX) to maintain desired therapeutic drug levels in the individual patient's regimen. Both web- based applications are available to support the dosing of infliximab for all approved indications.

At Baysient, we recognize that all patients are unique and require therapy tailored to fit them. Reduce dose-response uncertainty, decrease unwanted immunogenicity rates, and place clinical decision making back in the hands of the physician with Baysient's revolutionary software, T3 and iDose.

(800) 340-5377 | info@baysient.com



How T3 and iDose Work

The individualized dosing information from T3 and iDose expand the range of treatment options for consideration by the physician and patient. The dosing information is specific to each individual patient and data is configured by a series of patented algorithms produced by Baysient software and cannot be obtained elsewhere. The physician becomes the sole source of the individualized dosing options, and iDose and T3 provide the physician and patient with access to relevant data for making informed health care decisions, like those stated in Section 1554 of the Patient Protection and Affordable Care Act, Access to Therapies.

Graph Outputs in iDose and T3

The graphic outputs of T3 and iDose are designed as focal points for discussion between the physician and patient when making informed medical decisions. For example, how long the drug stays in your [the patient's] system is just as important as the amount of drug given.

According to research conducted by Marla Dubinsky M.D. and founder of Baysient LLC, Diane Mould PhD, FCP, FAAPS, "The use of PK dashboards to optimize IFX induction dosing is feasible in a real world setting and demonstrates that the majority of IBD patients required AD by INF4 regardless of mg/kg dosing and noncompliance is associated with [an] 11 fold increase in ATI [antibodies to infliximab] formation."

For patients in maintenance, a recent study, based Anne Strik M.D. and Diane Mould PhD, FCP, FAAPS, on the Efficacy of dashboard driven dosing of infliximab in inflammatory bowel disease patients found that:

> *"The [iDose] dashboard offers guidance on not only the IFX dose to be given, but also on the most optimal date for the infusion. Conveniently, it is possible to change this date based on the patient's or physician's discretion, e.g., during vacation times, because the dashboard offers dose recommendation[s] for other potential infusions dates. ...The training that is needed does not take more than a couple of hours, so it can be anticipated that implementation in clinical practice could happen without foreseeable problems."*

Compliance should be addressed during the decision making (i.e. informed consent) encounter.

T3 Time to Target

BILLING AND REIMBURSEMENT

FDA-Regulated — Decision Support Software

T3 and iDose are regulated by the FDA as "decision support software." When used by or under the supervision of a health care professional, FDA clearance is not required provided that the HCP understands the relationship between drug half-life and trough concentration.

T3 and iDose are intended to be used by physicians who consider it a medical necessity for patients to maintain minimum therapeutic IFX concentrations for the entire dosing interval.

T3 and iDose are not substitutes for the clinical reasoning required to evaluate the relationship between trough concentration and clinical outcome. The use of T3 and iDose may foster a shift in clinical reasoning away from "dose" to evaluating "trough concentration" relative to clinical outcome. With T3 and iDose, clinical decision making is now back in the hands of the physician.

Clinical Differences Between T3 and iDose

The main difference between iDose and T3 is that iDose supports both maintenance and induction therapy, including week 0 dosing. iDose calculates dosing regimens from an iDose-generated individual patient concentration vs time profile. iDose can have a concentration sample taken at any time post dose; T3 requires a trough concentration. iDose can provide a dose recommendation even without a trough concentration. The flexibility of iDose provides timely information that is necessary during induction and maintenance. T3 calculates respective dosing intervals for 5, 7.5, 10, and 15 mg/kg IFX doses from a T3-calculated individual patient's IFX half-life. T3 is limited to maintenance therapy only, with patients having regular dosing intervals of at least four (4) weeks.

Neither T3 nor iDose provide the desired minimum therapeutic IFX concentration (e.g., target trough concentration associated with beneficial clinical outcome). This target must be derived using clinical reasoning by the physician and inputted along with other patient specific information. Unlike publicly available dosing flow charts, both T3 and iDose provide specific recommendations for dose and respective dosing interval for individual patients.

T3 Time to Target

Price, Billing and Reimbursement

Both T3 and iDose are modestly priced tools used in medical decision making (MDM). Their indirect cost is offset by the physician's enhanced ability to provide complex reimbursable evaluation and management (E/M) services that cannot be performed in a timely manner without the software. The software allows complex analysis of individual patient data including test results, documentation of the analysis, and provides statistically sound and scientifically appropriate evidence for prior authorization requests.

The current (3/9/2021) AMA E/M guidelines provide new CPT® codes for MDM. The new codes may be used for reimbursement of time or MDM complexity. Tests and subsequent analysis ordered in an encounter may be counted in that encounter. When tests are ordered outside of an encounter they may be counted in a subsequent encounter when the results are analyzed.

The guidelines provide a matrix of requirements that coordinate ordering tests, analytical complexity, disease severity, and treatment risk. Table 1 is a summary of matrix results when using T3 or iDose with trough concentrations in the treatment of patients in maintenance, or with moderate or severe ulcerative colitis (UC) with IFX (example only).

Table 1: Summary MDM Reimbursement Matrices (IFX, UC)

Baysient Product	Disease Severity	E/M CPT®	NPA (non-facility)
T3 or iDose	Maintenance	99213-25	$92.05
iDose	Moderate	99214-25	$129.77
iDose	Severe	99215-25	$183.07

Both iDose and T3 are clinically validated and provide complex (i.e. pharmacometric) analysis for each respective patient's pharmacologic attributes. This analysis is of a higher complexity level than CPT code 99211. When following the correct CPT codes using iDose or T3 adds ancillary income with each use.

For tests and subsequent analysis ordered on the same day as IFX administration, the Medicare Claims Processing Manual states:

> *"…when a medically necessary, significant, and separately identifiable E/M service (which meets a higher complexity level than CPT code 99211) is performed, in addition to one of these drug administration services, the appropriate E/M CPT code should be reported with modifier -25. Documentation should support the level of E/M service billed. For an E/M service provided on the same day, a different diagnosis is not required."*

Compliance with all payer requirements must be assured prior to submitting any claim. The E/M codes listed in table 1 may not be submitted with other care or medication management claims for the same services. Review of claims by a billing professional (e.g. compliance officer) prior to submission is recommended.

With iDose
30 Day Free Trial

$1000/Annual Facility Fee
$50 per use/per day

Unlimited Physicians
Unlimited Use Per Patient/Day

With T3

$100 per month/per user

Unlimited Number of Patients
Unlimited Use Per Patient

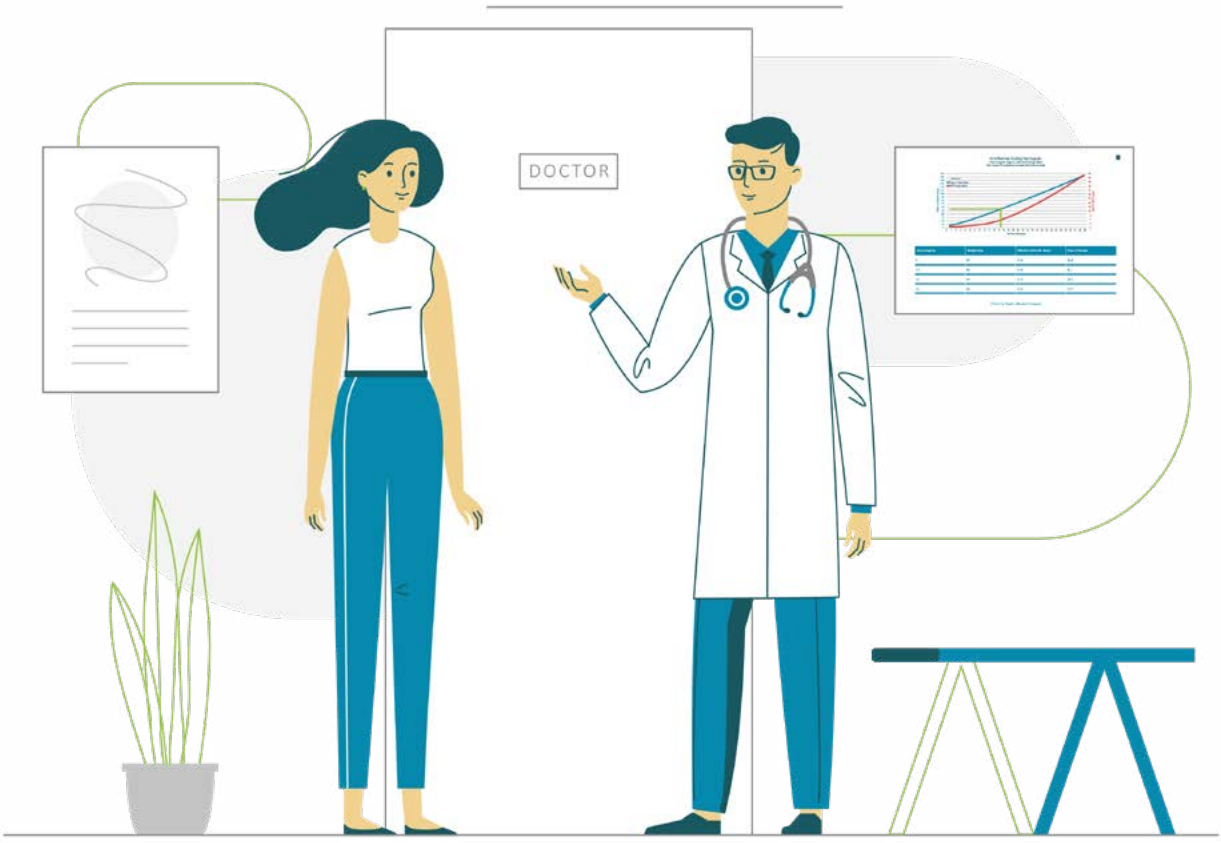
For Enterprise Pricing

Call: (800) 340-5377

(1). Dubinsky M, Phan BL, Tse S, Mould DR. 240 Real-world application of an adaptive dosing dashboard reveals accelerated induction dosing of infliximab is necessary in most IBD patients and improves therapeutic outcomes. Gastroenterology. (2020) 158:S47–8. doi: 10.1016/S0016-5085(20)30801-5

(2). Anne S. Strik, Mark Löwenberg, Diane R. Mould, Sophie E. Berends, Cyriel I. Ponsioen, Jan M. H. van den Brande, Jeroen M. Jansen, Daniël R. Hoekman, Johannan F. Brandse, Marjolijn Duijvestein, Krisztina B. Gecse, Annick de Vries, Ron A. Mathôt & Geert R. D'Haens (2021) Efficacy of dashboard driven dosing of infliximab in inflammatory bowel disease patients; a randomized controlled trial, Scandinavian Journal of Gastroenterology, 56:2, 145-154

(3). AMA E/M Guidance Dated 1/1/2021 with 3/9/2021 technical corrections (https://www.ama-assn.org/system/files/2020-12/cpt-corrections-errata-2021.pdf)



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