MICROBIOME BANK LTD.
2 Brandon Road
Braintree, Essex, UK
CM7 2NL

SIS v7.1

Severity scale and normative dose axis

For healthcare professionals

Symptom Importance Scale — Severity Bands and Normative Dose Axis

Clostridioides difficile infection (CDI) — microbiota transplantation treatment protocol

MicroBiome Bank

v7.1 — 2026-08-09

Approved by Dr. Patay Gábor at 2026-08-09 08:08. This document is the MicroBiome Bank normative core for the severity classification of CDI and for the daily therapeutic dose. Every other document is to be bound to it, and may not contain its own band or dose definition.

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Document details

Version	Status	Approved by	Approval timestamp
7.1	Approved	Dr. Patay Gábor	2026-08-09 08:08

What is this document about? This document is the MicroBiome Bank normative core for the treatment of CDI. Defined below are the daily density unit as a therapeutic quantity, the seven-level severity scale with a mandatory starting dose and an escalation band maximum, the service portfolio, the rules of escalation and LOT switching, the minimum course length and the gate to dose reduction. If a band boundary or a dose differs in any other document from what is set out below, the provisions of this present SIS v7.1 Severity Scale shall prevail. The scoring methodology of the questionnaire is contained in the SIS v7.1 Clinical Guide, and the full clinical context of the therapy in the Clinical Protocol Guide.

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Contents

Scope

This document is the single normative source of MicroBiome Bank for the severity classification of CDI and for the daily therapeutic dose. Every other document — clinical guide, patient booklet, questionnaire, website — is to be bound to it, and may not contain its own band or dose definition.

Binding rule: every system must bind to the level number or to the SIS range, never to the category name. The names shifted twice during the elaboration of v7.1.

Supersedes

- The SIS v6.1 treatment table (2026-03-11);
- the Clinical Protocol Guide EN v2.1 (2026-05-06) and HU v2.1 (2026-05-12);
- The five-band version of the vault markdown of 2026-05-26;
- The dose ladders I.2 and IV.1 of the DiffBiome Manual;
- The six-band curve legend of the CDI page;
- The eight values of the Recommendation column;
- The five-band recommendation of the CDI Treatment Protocol v3.0 r1.

I. The normative quantity: the density unit

The capsule count in itself is not a therapeutic quantity, because the density of the preparations varies between 5× and 50×. The protocol fixes the daily microbiota dose taken in density units, and the capsule count is derived from it.

1 density unit = 1 capsule of 1× density (denoted by the Roman numeral (I)), that is, 1/1200 of the dry-matter content of the 150 g reference donation.

Notation	Factor	Capsules / 150 g donation	In use in v7.1
I	1×	1200	no
II	2×	600	no
V	**5×**	**240**	**yes**
X	10×	120	no
XX	**20×**	**60**	**yes**
L	**50×**	**24**	**yes**

Daily density units = daily capsule count × density factor.

I.1 The clinical anchor of the scale

24 capsules of density “L” = 1200 density units = the quantity corresponding to one complete traditional faecal transplantation.

This is what gives the scale its meaning: every daily dose can also be expressed as the fraction of a traditional FMT performed with 150 g of stool to which it corresponds.

Level	Daily density units	As a proportion of one traditional FMT
2	5 → 10	approx. 1/240 → 1/120
3	10 → 15	approx. 1/120 → 1/80

4	15 → 20	approx. 1/80 → 1/60
5	20 → 30	approx. 1/60 → 1/40
6	60 → 100	approx. 1/20 → 1/12
7	**250**	**approx. 1/5 per day**

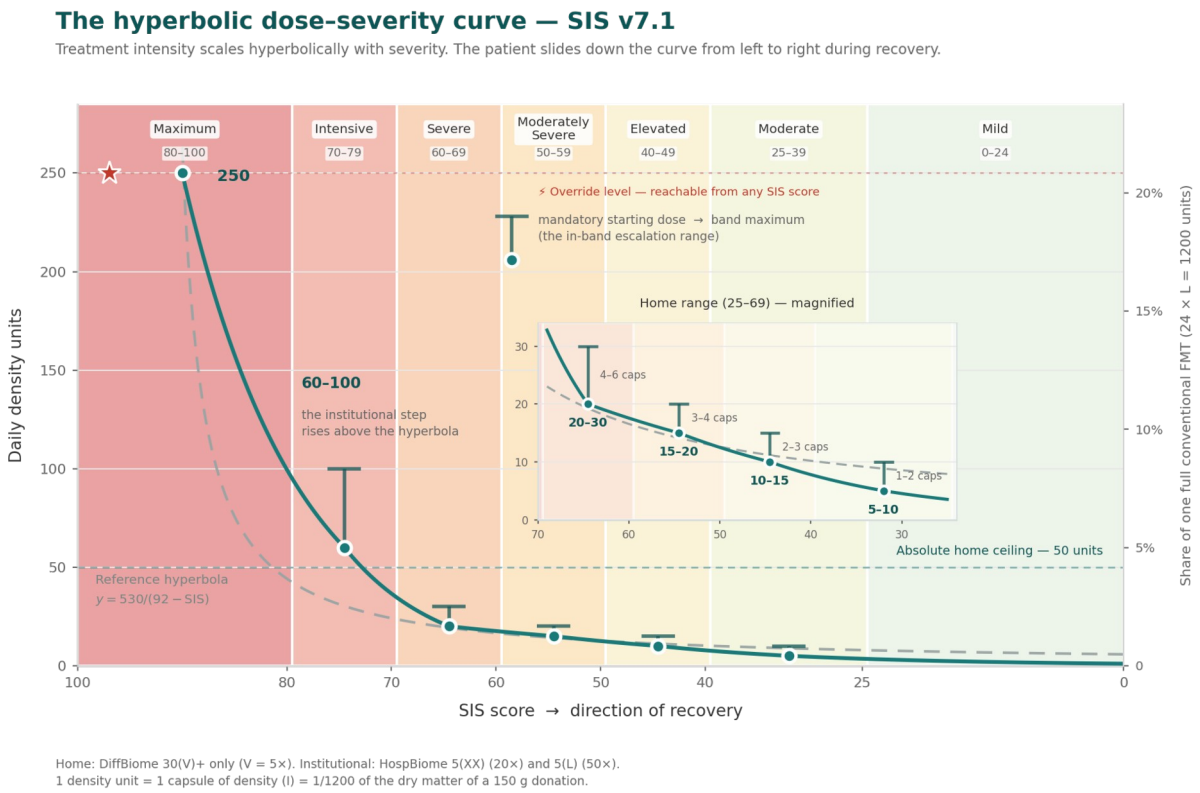

Figure 1.1 — Hyperbolic dose–severity curve (SIS v7.1). The daily microbiota dose is fixed in density units; the capsule count derives from it. The dot marks the mandatory starting dose, the vertical bar the band maximum available if the patient does not respond. The faint dashed line is the reference hyperbola, y = 530/(92 − SIS), which shows the principle behind the dose ladder. The maximum dose sits against the y-axis; as the patient recovers the SIS score falls and they "slide down" the curve from left to right.

I.2 Density equivalence in clinical practice

When changing preparation — in escalation and in dose reduction alike — the clinician calculates the density equivalent (density × capsule count), and raises or lowers within that. Viewed in capsule counts, the same step is sometimes an eightfold increase, sometimes a reduction — which is why the capsule count in itself cannot be used as a basis for decision.

II. Service portfolio

II.1 Home care

Preparation	Density	Pack size	Role
DiffBiome 30(V)+	V (5×)	30 capsules	The only home preparation. Homogenised graft in capsule form, collected over several days from the same donor.

No other preparation may be administered in the home setting. DiffBiome exists only in the "+" version.

The absolute home ceiling is 10 capsules/day (50 density units). This is not a band dose but a hard upper limit; it arises only in exceptional situations, under medical supervision. It deliberately does not appear in the treatment matrix.

II.2 Institutional care

Preparation	Density	Pack size	Role
HospBiome 5(L)	L (50×)	5 capsules	Entry point at level 7. It may be opened as required and administered mixed in a neutral liquid, including via nasogastric tube. This is an option, not a requirement.
HospBiome 5(XX)	XX (20×)	5 capsules	Entry point at level 6; the first dose reduction step of a therapy started at level 7.
HospBiome 5(V)	V (5×)	5 capsules	Late hospital phase; transition to the home preparation.
HospBiome 15(V)	V (5×)	15 capsules	The same capsule as the 5(V) — only the size of the pack differs. An economy pack size designed for Hungary.

Pack size ≠ therapy. The 5(V) and the 15(V) are clinically identical. Pack size is a matter of procurement quantity and unit cost, and may not appear in the treatment matrix, in the questionnaire, in the patient booklet or in the recommendation.

II.3 Intake regimen

The intake regimen is a property of the portfolio, not part of the description of a single preparation. The daily capsule count and the course length do not belong here — those are set out by chapters III. and V. The mode of intake:

- first thing in the morning, on an empty stomach, with plenty of water, swallowed whole — not to be chewed and as a rule not to be opened.
- approximately 30 minutes later, further fluid intake is recommended for adequate hydration, at least 2 dl.
- not to be administered together with alcoholic or hot liquids.
- antibiotics: administration of the antibiotic must be completed at least 48 hours before the start of the course. Antibiotic treatment started during the therapy warrants suspension of the course. Alongside antibiotics it may be administered only in a life-threatening situation, following prior consultation and at an increased dose.
- probiotics are to be discontinued during the course, unless the treating physician orders otherwise.
- Short-term storage: unopened bottle in a refrigerator, in a dark place, standing upright.
- Long-term storage: in a freezer, in an unopened bottle.

The same regimen applies to institutional preparations. "By default" refers to the route of administration: under ordinary circumstances the preparation is not given through a nasogastric tube. Opening the capsule is permitted in two situations — when the patient's severe condition requires the preparation to be given through a tube, and when the patient is unable to swallow the capsule; in the latter case the lesser-evil principle applies: we accept that efficacy decreases during intake. When opened, the contents may be administered mixed in a neutral liquid.

III. The seven-level severity scale

#	SIS	Name	Care setting	Preparation	Starting dose	Band max.	Density units
1	0–24	Mild	Home observation	—	—	—	—

2	25–39	Moderate	Home treatment	DiffBiome 30(V)+	**1**/day	2/day	**5 → 10**
3	40–49	Elevated	Home treatment, with medical consultation	DiffBiome 30(V)+	**2**/day	3/day	**10 → 15**
4	50–59	Moderately Severe	Home treatment, with close supervision	DiffBiome 30(V)+	**3**/day	4/day	**15 → 20**
5	60–69	Severe	Hospital assessment; may be continued at home	DiffBiome 30(V)+	**4**/day	6/day	**20 → 30**
6	70–79	Intensive	Hospital treatment	HospBiome 5(XX)	**3**/day	5/day	**60 → 100**
7	80–100	Maximum	Immediate hospital admission	HospBiome 5(L)	**5**/day, min. 3 days	—	**250**
⚡	over-ride	HospBiome override	Immediate hospital admission	HospBiome 5(L)	**5**/day	—	**250**

The ladder in density units: home 5 → 10 → 15 → 20 → 30 ‖ institutional 60 → 100 ‖ 250. Monotonic, gapless, with a closed upper limit.

III.1 Why a starting dose and a band maximum, not a range

Administration of the starting dose is mandatory — the course begins with it, and it is this that goes into the patient recommendation. The band maximum is exclusively an escalation value, in the case of non-response within the band. In the home bands the band maximum and the starting dose of the next level coincide: the non-responding patient may be raised up to the starting dose of the next level; beyond that, reclassification is required, not a further dose increase.

III.2 The jump between levels 5 and 6

The top of level 5 is 30 units, the bottom of level 6 is 60. The twofold jump is bound up with the change of setting: at level 6 the patient is in an institution, where the higher-density preparation and parenteral fluid replacement are immediately available. The absolute home ceiling of 50 units falls into this gap and fulfils a transitional role — but it is not a band dose.

IV. Escalation, LOT switch, dose reduction

IV.1 Home bands (levels 2–5)

Step	Trigger	Action
1	—	Start at the starting dose of the band.
2	Beyond 48 hours the daily stool count does not decrease	Raise to the band maximum.
3	There is no response even at the band maximum	Two equivalent options, both may be attempted: dose increase up to the starting dose of the next level, or LOT switch.
4	There is no response even after these	Re-administration of the SIS and reclassification — not a further dose increase.

5	Non-response persisting at 10 capsules/day (50 units)	Institutional referral.
⚡	Hard override criterion	The patient moves immediately into the override band.

The LOT switch is not warranted only in the case of repeated recurrence: primary non-response may in itself be a donor–recipient matching question.

The geometry of non-response makes a vertical correction necessary. In the case of non-response, the patient is situated below the hyperbola at the given SIS score: the daily density units actually received are lower than what the given severity would require.

The correction therefore takes place along the vertical axis: the dose is raised, at an unchanged SIS score, up to the band maximum. The patient does not move horizontally, because their condition has not become more severe — the classification is correct, it was the dose that was insufficient.

Horizontal movement comes into consideration only if there is no response even at the band maximum: the SIS must then be administered again, and if the new score falls into a higher band, the patient is reclassified. Reclassification is therefore a measurement result, not a dose decision.

IV.2 Institutional bands (levels 6–7) — the three axes of the HospBiome ladder

The apparent contradiction of the earlier editions stems from the fact that the ladder has three separate movements, and no edition set these out adequately.

Axis	When	What
Entry point	At classification	The SIS band decides it: level 6 → HospBiome 5(XX), level 7 → HospBiome 5(L).
Escalation	Exclusively in the case of non-response	Upwards, calculated in density equivalence. At level 6, 5(XX) 3 → 5/day, then 5(L) in the case of non-response. The LOT switch is an equivalent alternative here as well.
Dose reduction	In response to the patient's improvement	Downwards: 5(L) → 5(XX) → 5(V). Switch to 5(XX) if the stool frequency has demonstrably decreased and the patient can take fluids per os.

Discharge: DiffBiome 30(V)+ at 4 capsules per day (the starting dose of level 5), then dose reduction according to chapter V.

IV.3 Re-scoring the SIS

Re-administration of the SIS is recommended in the case of non-response. The protocol deliberately does not prescribe a fixed interval: the timing of re-scoring is a clinical decision.

This is not a missing rule but an explicit self-limitation. A formulation of the “at determined intervals” type is misleading, because it suggests that an unwritten calendar exists. The outcome of re-scoring is pathway reclassification or a band change; the latter follows automatically from the new score, without a separate threshold.

IV.4 Pathway reclassification

Trigger	From → To	Action
The SIS falls below 40 in a patient on the	Acute CDI → General dysbiosis	Transition to the dysbiosis protocol;

CDI protocol		FindBiome compatibility test for the personalised TransferBiome treatment.
The SIS reaches or exceeds the band between 50 and 60 points in a patient on a dysbiosis or IBS/IBD protocol	Dysbiosis / IBS / IBD → Acute CDI	Transition to the CDI protocol. Prescription of DiffBiome or HospBiome on the basis of the score. Close medical supervision is required.
The SIS remains persistently below 40 after a CDI episode	Acute CDI → return to the original protocol	Continuation of the FindBiome / TransferBiome process, if applicable. Continuation of SIS monitoring.

The band between "50–60" points is an indeterminate value, which the source document also refers to in that form. During the administration of the SIS it is to be narrowed to a single, specific score, which underpins the clinical decision.

IV.5 Soft override

Condition	Minimum classification
A-SIS ≥ 30	Level 5 (60–69, Severe)
A-SIS ≥ 38	Level 6 (70–79, Intensive)

Hierarchy: hard override > soft override > score. The seven-level scale is the precondition of this mechanism: the thresholds are tied to the 60 and 70 band boundaries.

According to the statement of SIS v6.1 itself, the thresholds (30, 38) are not ROC-optimised. This must be emphasised in every related document.

V. Course length and dose reduction

The pace of dose reduction is set by the patient's condition, not by a suggested schedule.

In the earlier materials three mutually contradictory fixed day ladders existed (10/20/30 days · 5/7–8/10 days · "from day 20"). All three misleadingly tied to a number of days what was in fact a symptom-based criterion.

V.1 Minimum course length

The minimum course length is 10 days at the starting (or escalated) dose in every band. Below this, dose reduction is not recommended, regardless of how quickly the patient improves.

V.2 Gate to dose reduction

Every one of the conditions must be met:

Criterion	Requirement
Elapsed time	≥ 10 days at the starting dose
Bristol trend	Has moved persistently from the baseline 6–7 range towards 5–6, and then 4–5
Stool volume / count	The extreme daily stool count has substantially decreased compared with baseline
Blood in the stool	None

The trend of the Bristol scale and the stool count are to be read together: the improvement of the Bristol value in itself, without a decreasing stool count, is not sufficient.

V.3 The course of dose reduction

- −1 capsule every 3–4 days, as long as the gate holds.

- If, according to the Bristol scale, the stool consistency returns to level 6–7, or the stool count rises: the dose must be returned to the band maximum, held there, and a LOT switch should be considered.
- Follow-up 1–2 weeks after the last dose.
- With a high P-SIS, premature discontinuation is the most frequent cause of relapse. The decrease of the P-SIS lags weeks to months behind the A-SIS, and this determines the duration of the maintenance phase.

V.4 Patient diary

The diary is kept at daily level, and the data set to be recorded is determined by the "Data" block of the DiffBiome Manual. The protocol does not define a separate, narrower data set — the dose reduction gate reads the Bristol value and the daily stool count from this diary.

If the diary data set of the Manual changes subsequently, it is the input of the protocol that changes, and it may not create a parallel list. The presence of the Bristol scale, the daily stool count and the bloody stool field is a basic requirement.

V.5 Box requirement

Level	SIS band	Estimated box requirement
2	25–39	1 box
3	40–49	1–2 boxes
4	50–59	2 boxes
5	60–69	3–5 boxes
6–7	70–100	institutional stock

DiffBiome 30(V)+, 30 capsules/box. Calculated with a 10-day starting phase and a one-capsule reduction every 3–4 days; escalation and the LOT switch increase it. This must be emphasised in every patient material.

VI. Cell-by-cell source anchoring

The precondition of auditability is that every number either comes from a source or is marked as calculated.

Level	SIS v6.1	CPG (HU v2.1 / EN)	v7.1	Status
2 · 25–39	4 u.	10 u.	5 → 10	derived — falls between the two ladders
3 · 40–49	6 u.	15 u.	10 → 15	derived — upper limit = CPG
4 · 50–59	10–15 u.	20–25 u.	15 → 20	derived — the meeting point of the two ladders
5 · 60–69	15 u.	30 u.	20 → 30	derived — the band maximum = the CPG value
6 · 70–79	5(V) 3–5/day = 15–25 u.	without a number	5(XX) 3–5/day = 60 → 100	reclassified — the v6.1 value is the dose reduction phase of level 6
7 · 80–100	100 → 250 u.	100 u.	5(L) 5/day = 250	from source
⚡	250 u.	—	250 u.	taken over from source
Home ceiling	—	—	10 capsules/day = 50 u.	**calculated — in the text only**

VII. Legal notice

The SIS is a decision-support and not a decision-making instrument. Automated category classification may never be carried out without medical review. Treatment decisions are made under medical supervision; the score provides guidance only.

The internal, prospective validation of the SIS is under preparation. The thresholds of the soft override are not ROC-optimised, and the P-SIS ≥ 22 threshold is empirical. The instrument is to be interpreted as a clinical tool refined through continuous use, not as a fixed scoring rubric.