THE
Health Clinic

CLINICAL STANDARD OPERATING PROCEDURE

TBE Vaccination Protocol — Encepur

Tick-borne encephalitis vaccination aligned with Folkhälsomyndigheten, Smittskydd Stockholm, and Svenska Infektionsläkarföreningen — for adult and adolescent patients.

DOCUMENT
SOP-VAX-001 — TBE / Encepur

VERSION
1.1 · May 2026

AUDIENCE
Clinical staff — physicians & nurses

CLINICAL LEAD
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ISSUED BY
The Health Clinic Stockholm

REVIEW CYCLE
Annual, or upon guidance update

Purpose & scope

Standardised process for the administration of Encepur Adult against tick-borne encephalitis (TBE) at The Health Clinic Stockholm, aligned with Swedish national guidance.

This SOP applies to all patients aged 12 years and over receiving Encepur Adult (1.5 µg / 0.5 mL, intramuscular) for the prevention of TBE. It defines schedule selection, administration, follow-up, recall, and documentation. The protocol follows **Folkhälsomyndigheten** national recommendations (issued May 2026), **Smittskydd Stockholm** guidance (fact-checked January 2026), and **Svenska Infektionsläkarföreningen** guidelines (revised July 2025). Where Swedish practice diverges from the Encepur Summary of Product Characteristics, Swedish practice prevails.

4 licensed schedules	≥97% seroconversion after primary series
12+ years adolescent & adult use	0.5 mL IM deltoid

SWEDISH PRACTICE — KEY DIVERGENCES FROM SMPC

Age ≥ 50 and immunocompromised patients receive an extended 4-dose primary series (Day 0, 1 month, +1–2 months, 5–12 months). This is a Swedish national addition not in the Encepur SmPC, based on reduced seroconversion in older adults.

Dose 3 spacing is 5–12 months after dose 2 (Folkhälsomyndigheten), not 9–12 months (Encepur SmPC). The Swedish interval applies to The Health Clinic Stockholm patients.

Express schedule (Day 0 / 7 / 21) is contraindicated in immunocompromised patients per Smittskydd consensus across Swedish regions, regardless of SmPC licensing.

01 TBE risk areas — Sweden

Folkhälsomyndigheten classifies Swedish municipalities into three risk areas based on TBE incidence:

- **Risk area 1** — moderate-to-high TBE prevalence. Vaccination recommended for adults and children from age 3 who risk tick bites. Covers most of Götaland, Svealand, and parts of Gävleborg.
- **Risk area 2** — low prevalence. Vaccination recommended for immunocompromised individuals living in or visiting the area, or adjacent municipalities.
- **Risk area 3** — very low or no prevalence. Generally most of Sweden north of Dalälven.

Stockholm county, Södermanland, and Uppsala län — particularly coastal areas and around Mälaren — are among the highest-incidence regions in Sweden. **Smittskydd Stockholm recommends TBE vaccination to all adults and children spending time in nature in Stockholm län.** Roughly 250–350 patients are hospitalised with TBE in Sweden annually.

02 Vaccination schedules

SCHEDULE	DOSE 1	DOSE 2	DOSE 3	DOSE 4	1ST BOOSTER	WHEN TO USE
Standard *Age < 50, immunocompetent*	Day 0	1–3 months	5–12 months after dose 2	—	3 years after dose 3	Default for healthy adults < 50. Ideally start in cold season.
Extended *Age ≥ 50 or immunocompromised*	Day 0	1 month	+1–2 months after dose 2	5–12 months after dose 3	3 years after dose 4	Mandatory for all patients ≥ 50 at start of vaccination, and for immunocompromised adults regardless of age.
Rapid *Fast conventional*	Day 0	Day 14	5–12 months after dose 2	—	3 years after dose 3	Faster initial protection; dose 3 can complete in winter. Healthy adults < 50 only.
Express *SmPC-licensed, restricted use*	Day 0	Day 7	Day 21	—	12–18 months after dose 3	Imminent travel, occupational or diplomatic urgency. Healthy adults < 50 only. **Contraindicated in immunocompromised.**

> **CRITICAL — EXPRESS SCHEDULE BOOSTER TIMING**
>
> Patients on the Express schedule receive their first booster at **12–18 months** after dose 3, not at 3 years. This is the single most common documentation error and must be flagged at every Express dose 3 appointment.

03 Subsequent boosters & onset of protection

SUBSEQUENT BOOSTERS (PER SVENSKA INFEKTIONSLÄKARFÖRENINGEN)

- **All ages after primary series:** first booster 3 years after the last primary dose (or 12–18 months for Express).
- **Age < 50 with ≥ 4 doses before age 50:** subsequent boosters every 5–10 years, individualised.
- **Age ≥ 50 or vaccinated after age 50:** subsequent boosters every 5 years.
- **Immunocompromised:** every 3–5 years; consider post-booster serology.

ONSET OF PROTECTION

- **Standard / Rapid:** seroconversion expected ≥ 14 days after dose 2 (~ 2 months from initiation). Maximum protection after dose 3 at 5–12 months.

- **Extended (≥ 50 / immunocompromised):** protection builds across 4 doses; full protection after dose 4 at ~ 6–12 months.
- **Express:** ~ 97% seropositivity 3 weeks after dose 3 — maximum protection by ~ 6–7 weeks from initiation.

04 Patient selection algorithm

Apply at booking. Age and immune status determine the schedule before exposure horizon.

DECISION POINT	RECOMMENDED SCHEDULE
Age ≥ 50 at start of vaccination	**Extended** — 4-dose series (Swedish standard). Do not use Express.
Immunocompromised (any age)	**Extended** — 4-dose series. Express contraindicated. Consider serology check 4 weeks after final dose.
Healthy < 50, travel or exposure within **8 weeks**	**Express** — Day 0 / 7 / 21. Inform patient of 12–18 month booster.
Healthy < 50, exposure within **2–6 months**	**Rapid** — Day 0 / 14 / 5–12 mo.
Healthy < 50, no urgency (start October–February)	**Standard** — Day 0 / 1–3 mo / 5–12 mo.
Previously vaccinated, lapsed booster	Catch-up per §7. Generally no need to restart.
Pregnant / breastfeeding	Risk-benefit assessment by physician. Inactivated vaccine — likely safe; defer unless high exposure risk.

> **LATE INITIATOR IN TICK SEASON — AGE < 50**
>
> If a healthy patient under 50 starts vaccination during ongoing tick season (March–November) and needs protection within ~ 2 months, choose Rapid over Express where possible. Two doses 14 days apart give reasonable protection within 2 weeks of dose 2; this matches the standard Swedish "snabbschema" recommendation. Reserve Express for cases where the patient truly cannot return between Day 0 and Day 21 — typically embassy and travel patients with fixed departure dates.

05 Clinical process

1 Booking & pre-screen

Reception or nurse

- Confirm indication (travel, occupational, residence in risk area), planned exposure dates, and prior TBE vaccination history.
- Record age and screen for immunosuppression (medications, conditions) — this determines schedule choice.
- Flag allergies: egg / chicken protein, neomycin, gentamicin, formaldehyde, latex (needle shield contains natural rubber).
- Verify no acute febrile illness. Defer if temperature > 38 °C.
- **Book all primary doses + first booster at the same time** — Extended schedule requires four appointments plus booster; book all five up front.
- Send all dates to the patient's calendar via SMS / iCal invite.

2 Pre-vaccination consult

Physician or nurse

- Document indication, chosen schedule, and rationale in Webdoc — explicitly note if Extended schedule applies and why (age ≥ 50 or named immunosuppressive condition / medication).
- Review medications, immunosuppression status, pregnancy / breastfeeding.
- For international patients: explain that the Swedish schedule may differ from their home country (4 doses for ≥ 50, etc.) and that this reflects Folkhälsomyndigheten guidance.
- Informed consent — discuss expected reactions: local pain or swelling, low-grade fever, fatigue 1–3 days, influenza-like symptoms within 72 hours (particularly after dose 1), rare allergic reactions.
- Explicitly explain schedule-specific booster timing — 12–18 months for Express vs. 3 years for all other schedules.
- Provide branded written information sheet — never on loose paper.

3 Administration

Nurse

- Site: deltoid muscle, intramuscular, 0.5 mL.
- Never gluteal — reduced immunogenicity.
- Shake suspension before drawing.
- Observe patient 15 minutes post-injection — vasovagal and anxiety reactions documented in SmPC.
- Document in Webdoc: lot number, expiry, site, dose number, schedule type.
- Enter into the schema for invoicing — every patient interaction must be entered.

4 Between doses

Automated

- Automated SMS / email reminder 48 hours before each appointment (Pipedrive / Twilio workflow).
- After dose 1, send written aftercare information and the contact route for adverse events.

5 At completion of primary series

Physician or nurse

- **Book the first booster now** — directly into Webdoc and the patient's calendar.
    - Express: 12–18 months
    - Standard / Rapid / Extended: 3 years after last primary dose
- Trigger automated booster reminder workflow.
- **Immunocompromised and age ≥ 60 patients:** offer serology check (NT or ELISA) 4 weeks after final primary dose. Administer additional dose if NT < 10.
- Issue a formal vaccination certificate on letterhead — essential for diplomatic and embassy patients.

6 Recall system

CRM / automation

- At final primary dose: schedule first booster recall entry.
- After first booster: schedule subsequent boosters every 5 years (age ≥ 50, immunocompromised, or vaccinated after age 50), or every 5–10 years (age < 50 with ≥ 4 doses before 50).
- Build into Pipedrive nurture loop so recall is automatic, not manual.

06 Special situations

SITUATION	ACTION
Age ≥ 50 starting vaccination	**Extended 4-dose schedule mandatory** per Svenska Infektionsläkarföreningen. Day 0, 1 month, +1–2 months, 5–12 months, then booster at 3 years. Subsequent boosters every 5 years.
Age ≥ 50 who received only 3 doses initially	Top up with an extra dose at least 2 months after the most recent dose. After total 5 doses (across history), boosters every 5 years.
Immunocompromised (any age)	Extended 4-dose schedule. Express contraindicated. Common conditions: TNF-inhibitors, methotrexate, biologics, post-transplant, chemotherapy, advanced HIV. Consider serology check 4 weeks after final dose.
Egg allergy	Per SmPC, vaccination normally entails no increased risk in patients with egg allergy based on questionnaire or skin-prick test alone. Document and proceed with standard 15-minute observation. **Severe anaphylaxis to egg → defer and refer.**
Latex allergy	Needle shield contains natural rubber. Avoid, or remove the shield carefully without skin contact.
Pregnancy	No specific safety studies. Inactivated vaccine — most evidence suggests safety. Defer unless high exposure risk. Inadvertent vaccination during pregnancy is not a cause for concern.
Breastfeeding	Not a contraindication. Vaccinate as indicated.
Missed dose / interval lapsed	Generally no need to restart. Continue from where the patient left off. **Exception:** if vaccination was started after age 50 or during immunosuppression and only one dose was given, restart from the beginning.
Switching from FSME-Immun	Vaccines are interchangeable after the primary series. Where possible, complete the primary series with a single product. Note FSME-Immun's dose 3 spacing is 5–12 months from dose 2 — same as Swedish national guidance.
Acute febrile illness	Defer until resolved. Mild upper respiratory infection without fever is not a contraindication.
Children < 12 years	Use Encepur Children (0.25 mL) — outside the scope of this adult SOP. Refer to paediatric protocol.

07 Swedish vs. SmPC practice — patient-facing summary

For embassy, expat, and Cigna patients who may have been vaccinated abroad, this summary clarifies why Swedish practice differs from manufacturer labelling. Use it to explain decisions during the consult.

TOPIC	ENCEPUR SMPC (MANUFACTURER, EU)	SWEDISH NATIONAL PRACTICE (APPLIED AT THIS CLINIC)
Adults < 50	3-dose primary series	3-dose primary series — aligned
Adults ≥ 50	3-dose primary series	**4-dose extended series** — extra dose at +1–2 months after dose 2
Immunocompromised	Not specifically addressed; titre check suggested	**4-dose extended series**. Express contraindicated. Serology recommended.
Dose 3 spacing (standard)	9–12 months after dose 2	**5–12 months** after dose 2 (Folkhälsomyndigheten)
Express schedule	Licensed for all adults ≥ 12 years	Licensed but **not recommended for ≥ 50 or immunocompromised**
Subsequent boosters < 50	Every 5–10 years (SmPC May 2025)	Every 5–10 years for those with ≥ 4 doses before age 50
Subsequent boosters ≥ 50	Every 3 years (SmPC May 2025)	Every 5 years (Svenska Infektionsläkarföreningen)

> **WHY SWEDISH PRACTICE DIFFERS**
>
> The 4-dose schedule for older and immunocompromised patients is based on Swedish studies (notably the 2016 RCT in patients with rheumatoid arthritis on TNF-inhibitors and methotrexate) showing reduced seroconversion compared with younger, healthy adults. Sweden, Norway, Finland, Germany, and Austria have aligned around the same extra-dose recommendation. This is standard Nordic and Central European clinical practice, not a Swedish idiosyncrasy.

08 Documentation checklist

Each dose must record the following in Webdoc before the patient leaves the clinic:

- Indication, risk area assessment, and chosen schedule (Standard / Extended / Rapid / Express)
- Patient age and immune status at start of vaccination (drives schedule selection)
- Date and time of administration
- Lot number and expiry date
- Site (left or right deltoid)
- Dose number in series (1, 2, 3, 4, or booster)
- Administering clinician
- Any immediate adverse reactions observed during the 15-minute observation
- Next appointment date (booked, not provisional)
- Schema entry for invoicing

> **PATIENT COMMUNICATION STANDARD**
>
> Every patient must leave with: a branded vaccination card, the next appointment date in their calendar, and an information sheet on letterhead. Never use loose notepaper. After the primary series, issue a formal vaccination certificate.

09 Pricing & packaging

Bundle as a **TBE Protection Package** rather than per-dose pricing. A single package price encourages completion and reduces drop-off between doses — particularly important for the 4-dose Extended schedule.

- **TBE Standard Protection** — 3 doses (Standard or Rapid) + 3-year booster reminder service.
- **TBE Extended Protection** (≥ 50 or immunocompromised) — 4 doses + optional serology + 3-year booster reminder service.
- **TBE Express Protection** — 3 doses Day 0 / 7 / 21 + 12–18 month booster reminder service.

Include the vaccination certificate, recall service, and nurse access in the package value stack.

10 References

1. Folkhälsomyndigheten. Rekommendationer om vaccination mot TBE. Issued May 2026. folkhalsomyndigheten.se
2. Svenska Infektionsläkarföreningen. Riktlinjer för TBE-vaccination. Revised 2025-07-07.
3. Smittskydd Stockholm / Vårdgivarguiden. Information för vårdgivare om TBE-vaccination. Fact-checked 2026-01-16 (Charlotta Rydgård).
4. Encepur Adult — Summary of Product Characteristics (Sweden / MPA, docetp.mpa.se).
5. Encepur Adult — SmPC revised May 2025 (Germany), extending booster intervals to 5–10 years for ages 12–49.
6. Steffen R et al. Fast-Track to Protection? A Review of Encepur's Express Dosing Schedule for Tick-Borne Encephalitis. Viruses 2025; 17(11):1439.
7. Wittermann C et al. Sustained antibody persistence ≥ 15 years after booster vaccination — third 5-year follow-up. Vaccine 2023.
8. Schöndorf I et al. Tick-borne encephalitis vaccination: applying the most suitable vaccination schedule. Vaccine 2007; 25:1470–5.
9. Hertzell KB et al. Tick-borne encephalitis vaccine to medically immunosuppressed patients with rheumatoid arthritis. Vaccine 2016; 34:650–5. (Foundation for the Swedish 4-dose recommendation in immunocompromised.)
10. 1177 Vårdguiden. Vaccination mot TBE. Updated 2026.

APPROVED — CLINICAL LEAD

DATE