

Expanded Access and Emergency Use Policy

How a treating physician can request an unapproved Baxtra medicine for a patient who cannot wait.

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Owner	Chief Medical Officer
Applies to	All investigational medicines in the Baxtra portfolio

Expanded access is an exceptional route for an individual patient, not an alternative development programme and not a promise that an investigational medicine will be supplied. This policy explains how a treating physician can ask Baxtra to consider a request when the patient cannot wait for a clinical trial or approved therapy.

All medicines in the Baxtra portfolio are investigational. None has been approved by any regulatory authority in any country, and the safety and efficacy of none has been established. Baxtra's review is separate from FDA or IRB approval and does not replace the treating physician's clinical judgement.

Who may request

Only the patient's treating physician may make a request. The physician must be licensed and responsible for the patient's care, and must be able to supervise administration, monitoring and follow-up. A patient or family member may ask their physician about the possibility of expanded access, but may not submit a request directly to Baxtra.

This boundary is deliberate. A treating physician can assess the diagnosis, alternatives, urgency, contraindications, consent capacity and monitoring environment. Direct requests from patients or family members could expose private medical information, create false expectations about supply and bypass the physician, IRB and FDA controls that protect the patient.

Eligibility criteria

Baxtra will consider a request when all of the following are reasonably supported:

- The patient has a serious or immediately life-threatening disease or condition for which the requested investigational medicine is scientifically relevant.
- There is no comparable or satisfactory approved therapy available, or the available therapy is not suitable for this patient in the physician's judgement.
- The potential patient benefit justifies the potential risks, recognising that benefit is uncertain and has not been established.
- The patient is not eligible for, cannot access in time, or cannot reasonably enrol in a relevant clinical trial.
- The physician can obtain informed consent, meet FDA and IRB requirements, administer the medicine safely and provide required follow-up.

- Product is available, is within its quality and stability limits, and can be released without compromising a clinical trial or other patient's allocation.

Eligibility does not mean approval. It means the request is suitable for a documented review. Baxtra may ask for additional information or recommend a clinical trial, an approved alternative or supportive care instead.

No charge: Baxtra does not charge the patient or treating physician for investigational medicine supplied under an approved expanded-access arrangement. The physician and patient remain responsible for ordinary clinical-care costs, monitoring, facility charges and any costs imposed by a regulator or institution.

The request process

1. The treating physician identifies the patient's unmet need, confirms that a relevant clinical trial or approved therapy is not a workable option, and discusses the investigational nature of the request with the patient.
2. The physician submits the request through the authenticated Client portal at <https://baxtra.pages.dev/client/>. The submission must identify the medicine and indication, urgency, proposed dose and duration, monitoring plan and the physician's contact details. Patient information must be limited to what is needed for review and sent only through the secure route.
3. Baxtra acknowledges receipt, checks whether the submission is complete and assigns a medical and regulatory reviewer. The target response is within 3 business days of a complete request.
4. For a confirmed high-consequence pathogen exposure, the physician marks the submission "urgent PEP" and includes the laboratory or healthcare exposure confirmation. Baxtra targets a response within 24 hours of a complete request. The target is not a guarantee of supply or authorisation.
5. Baxtra reviews medical suitability, product availability, manufacturing and quality status, safety information, regulatory pathway and the proposed monitoring plan. It may ask focused clarification questions.
6. If Baxtra supports the request, the treating physician obtains the required FDA authorisation, IRB approval or emergency-use determination, informed consent and any institutional approvals before administration unless an applicable emergency exception permits a different sequence.
7. Baxtra releases product only after the required approvals and logistics checks are complete. The physician follows the agreed protocol, reports safety information and returns or destroys unused product as instructed.

Response clock

Request type	Target response	What the clock means
Complete standard request	3 business days	Initial decision to support, decline or request specific clarification; not a promise to ship.
Confirmed high-consequence pathogen exposure	24 hours	Urgent medical and supply review after a complete urgent-PEP submission; not a substitute for FDA or IRB action.
Incomplete request	Clock starts when complete	Baxtra identifies missing information as quickly as practicable; clinical care must not wait for an administrative response.

Information required

The treating physician should provide the minimum necessary information in the following categories:

Category	Examples
Patient and diagnosis	Age range, relevant sex, diagnosis or exposure, disease severity, key laboratory or imaging findings, onset and current trajectory.
Prior and available care	Approved therapies tried or considered, contraindications, clinical-trial availability and why waiting is not reasonable.
Request	Medicine and programme, proposed route, dose, schedule, duration, treatment objective and whether post-exposure prophylaxis is requested.
Safety plan	Relevant history, concomitant medicines, baseline tests, monitoring, stopping rules, adverse-event response and follow-up period.
Oversight	Physician licence and institution, IRB status or emergency pathway, consent plan, pharmacy and administration arrangements.
Urgency and logistics	Time by which a decision is needed, shipping destination, storage capability and any confirmed exposure documentation.

Do not send names, full clinical records or direct identifiers in ordinary email. Use the authenticated Client portal. If a portal problem prevents submission, send only a non-identifying request for a secure submission route through the website and state that patient details have not been attached.

How decisions are made

The Chief Medical Officer or delegated medical lead is accountable for the medical decision. A regulatory affairs reviewer assesses the applicable FDA pathway; Clinical Development or Medical Affairs reviews the scientific rationale; Quality and Supply Chain confirm product status; and Pharmacovigilance confirms the safety-reporting plan. Legal and privacy reviewers advise where required. No single reviewer may release product without the required cross-functional checks.

A request is assessed against the eligibility criteria, the proposed risk-benefit balance, the quality and stability of the specific lot, the ability to monitor the patient, the regulatory route and the effect on ongoing trials. A prior response to another request is not a precedent: patient circumstances, disease, exposure timing and product availability differ.

Possible decisions

- Support, subject to FDA, IRB, informed-consent and institutional requirements. The response states the conditions of supply, monitoring and reporting.
- Request clarification. The response identifies the missing information; the response clock restarts when the submission is complete.
- Decline. Baxtra gives the physician a reason from the refusal categories below, unless disclosure would compromise a patient's privacy, an investigation or a regulatory obligation.
- Hold for supply or quality review. A hold is not a clinical recommendation and does not mean the medicine is safe or effective.

Supply constraints stated plainly

Baxtra makes limited quantities of investigational medicine. Some programmes have very little drug product, and a queue is possible. A request may therefore be medically reasonable and still not be supplied. Allocation considers

clinical urgency, product quantity and stability, quality release, the ability to monitor safely, fairness among requests and the need not to interrupt an ongoing trial or reserve required for a public-health response.

Baxtra does not accept payment to move a request ahead of another patient. It does not auction supply, sell investigational product or promise a treatment date before quality and regulatory checks are complete. The treating physician is told whether the constraint is current stock, release testing, shipping, a study reserve or another documented reason.

Regulatory requirements

For a US single-patient expanded-access request, the treating physician generally works with FDA on a single-patient IND under 21 CFR Part 312, including the applicable Form FDA 3926 process and FDA permission before treatment unless an emergency exception applies. The physician must obtain IRB review or follow the emergency-use IRB process, obtain informed consent, comply with the authorised treatment plan and report required safety information. Baxtra provides product and sponsor information needed for the submission but does not replace the physician as the treating clinician.

The institution may impose additional pharmacy, biosafety, infection-control, credentialing or security requirements. If a non-US request is received, the local regulatory authority and ethics requirements apply; the US process does not automatically authorise treatment in another country.

Post-exposure prophylaxis after a laboratory or healthcare exposure

A request after a confirmed laboratory or healthcare exposure to a high-consequence pathogen is handled as an urgent medical review. The treating physician must first activate the institution's exposure-management and infection-control procedures and contact the relevant public-health authorities. Baxtra does not diagnose exposure, direct isolation or replace occupational health, infectious-disease or emergency care.

The physician should submit the exposure confirmation, date and type of exposure, source information that can lawfully be shared, the exposed person's symptoms and baseline status, the time-sensitive prophylaxis rationale, alternative measures taken and the proposed monitoring plan. Baxtra targets a response within 24 hours of a complete request. A laboratory or healthcare exposure alone does not guarantee eligibility, supply or benefit from an investigational medicine.

If supply is supported, the physician still must obtain the applicable FDA authorisation, IRB or emergency-use approval and informed consent, unless a legally recognised emergency sequence applies. The physician must follow the product-specific instructions, public-health direction and infection-control plan. New symptoms or a change from exposure to suspected disease require urgent clinical assessment; prophylaxis is not treatment and must not delay it.

The request record should say "confirmed high-consequence pathogen exposure" only when the physician has confirmation from an appropriate laboratory, occupational-health process or public-health authority. Do not use the urgent route to obtain priority for an unconfirmed concern.

Reporting obligations back to Baxtra

The treating physician and institution must report adverse events, serious adverse events, suspected unexpected serious adverse reactions, medication errors, lack of expected response, pregnancy where relevant and important new diagnoses according to the authorised protocol and applicable FDA and IRB requirements. The initial notification should be prompt; follow-up information should be supplied when available.

The physician must provide treatment dates, dose and lot information, clinically relevant laboratory and outcome information, protocol deviations, concomitant medicines and the final disposition of unused product. Reports should use the secure route and the patient's study or request identifier. Baxtra may ask for additional information to satisfy pharmacovigilance and regulatory duties, but it will request the minimum necessary data.

Contact routes

Route	Who uses it	Purpose and expected handling
Client portal: https://baxtra.pages.dev/client/	Treating physicians and authorised institutional staff	Standard requests, documents, secure clarifications and shipment coordination. Primary route.
Client portal — mark “urgent PEP”	Treating physician after confirmed high-consequence pathogen exposure	24-hour target response after a complete submission. Activate institutional exposure procedures first.
Baxtra website: https://baxtra.pages.dev/	Physician who cannot access the portal	Request a secure submission route without attaching patient details.
Disclosure mailbox: disclosure@baxtra.pages.dev	Public-document questions and transparency queries	Not a patient referral, not a clinical advice service and not a secure route for medical records.

Reasons a request will be refused

Baxtra will refuse a request, or decline to supply after initially reviewing it, for one or more of the following reasons:

- The requester is not the treating physician, cannot establish responsibility for the patient's care or asks Baxtra to bypass the patient's clinician.
- The patient does not have a serious or immediately life-threatening condition, or the requested medicine is not scientifically relevant to the condition or confirmed exposure.
- A comparable approved therapy is available and suitable, or a relevant clinical trial is reasonably available and the request does not explain why it cannot be used.
- The potential risks cannot be justified by the proposed circumstances, the patient's condition or the available information.
- The physician or institution cannot provide appropriate monitoring, emergency response, pharmacy control, infection control or follow-up.
- Required FDA authorisation, IRB review, informed consent or institutional approval cannot be obtained, or the proposed use is outside the authorised terms.
- The submission is materially incomplete, contains unreliable information, or the urgency claim cannot be confirmed.
- The requested lot is unavailable, cannot be quality-released or stored or shipped safely, is reserved for an ongoing trial or public-health response, or a queue prevents fair allocation.
- Supplying the product would compromise a clinical study, participant safety, manufacturing controls, regulatory obligations or a documented investigation.

A refusal is not a statement that the medicine will not help or that the patient's condition is not serious. It is a decision about whether this specific request can be supported safely, lawfully and responsibly with the information and product available at the time. The treating physician remains responsible for alternative care and urgent escalation.

Patient and family questions

Patients and families should speak with the treating physician about diagnosis, alternatives, clinical trials, expected risks and whether a request could be appropriate. Baxtra will not accept a direct patient application or provide individual treatment advice through this policy. A physician may share the outcome of a request with the patient in the context of clinical care.

Review and accountability

The Chief Medical Officer owns this policy. Expanded-access decisions, urgent PEP responses, supply holds, refusals and safety reports are recorded for internal review. The Disclosure Review Board clears the public revision; it does not make individual patient-treatment decisions. This public revision withholds three internal sections: product-specific manufacturing and release controls, site security and queue-level allocation records. Those sections are withheld to protect quality systems, facility security and patient privacy.

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