Teva Expanded Access Program (EAP) Request Form

Section I: EAP Request Details - To be completed Requester
Contact Information (Note "NA" for items not applicable.)
1. Name of physician or regulatory agency requestor:
2. Name of institution (if applicable):
3. Physician/institution address:
4. Physician phone number:
5. Physician email:
Proposal Information
6. Name of drug being requested:
7. Type of EAP: ☐ Patient ☐ Group Provide any applicable details of program scope (do not include any patient identifiable information or personal data):
8. Is a protocol attached? ☐ Yes ☐ No NOTE: If No, complete items 9-14 below. If Yes, items 9-14 do not need to be completed but this information must be included in the protocol. Please indicate "see attached" as appropriate.
9. Description of patient/patient group disease or condition(do not include any patient identifiable information or personal data):
10. Rationale for expanded access use of the drug:
11. Proposed patient/patient group treatment plan, including dose and duration:

12. Safety and efficacy data required to provide adequate evidence of an appropriate risk-benefit analysis and support the use of the investigational drug/biologic for the specific EAP:
13. Proposed Procedures for Safety Monitoring:
14. Proposed endpoint criteria (if any):
Physician and Site Experience and Capabilities
15. Is physician licensed and qualified to administer drug for expanded access use (provide pertinent information [e.g., or attach CV, medical license to email]):
16. Clinical trial experience of physician/site:
17. Investigational drug storage capability:

Drug Cost and Teva Expenses
18. Is free investigational drug requested?
19. Description of activities for which funding by Teva is being requested (e.g., administrative, monitoring by HCPs, IRB/EC fees, pharmacy fees, importation licenses)?

Once completed, email the request form to ExpandedAccess@tevapharm.com