Hypermunes Patient Assistance Program – Application

Check applicable product for which patient assistance is being requested:

HyperRAB ☐
(rabies immune globulin [human])

HyperTET ☐
(tetanus immune globulin [human])

HyperHEP B ☐
(hepatitis B immune globulin [human])

PATIENT INFORMATION

First Name: _____ Middle Initial: _____ Last Name: _____

Date of Birth: _____ Parent/Guardian: _____

Street Address: _____ Apartment Number: _____

City: _____ State: _____ Zip Code: _____

Household Income: _____ HH Size: _____

Social Security#: _____ Phone#: _____ Email: _____

Patient Certification

I agree I have no insurance coverage for Hypermunes at this time and insufficient financial resources to pay for the prescribed medication. I authorize Grifols, their agents, my healthcare providers, and third-party contractors or their service providers authorized to administer the Hypermunes Patient Assistance Program to: (1) use the information that I provided on this form to determine my eligibility for and assist with my continued participation in the Hypermunes Patient Assistance Program, (2) use my Social Security number to access my credit information and information derived from public and other sources to estimate my income in conjunction with the eligibility determination process, and (3) contact me to seek feedback on Hypermunes Patient Assistance Program services. I verify that the information provided in this application is complete and accurate to the best of my knowledge. I understand that if my health insurance coverage or employment status changes, I will notify the Hypermunes Patient Assistance Program promptly of such change. I understand that this may affect my eligibility to participate in the program before my eligibility period ends. I also understand that any and all information that I provide may be shared with my treating physician. I understand that this authorization will remain in effect throughout my participation in the program. I understand that I am approved for up to 30 days from the receipt of this application form. I understand that my access to Hypermunes within this program may be delayed depending on the number of participants and the availability of drug product for the program. The Hypermunes Patient Assistance Program may be discontinued or modified at any time, without notice. I understand that I am under no obligation to use or purchase any product or service as a condition of receipt of free product from Grifols, the manufacturer of Hypermunes. I shall not seek reimbursement from any sources for the free product that I receive, and I acknowledge that neither I nor any provider is entitled to reimbursement for free or replacement product.

Patient Signature (Parent/Guardian if applicable) _____ Date _____

Please return the completed form to confidential **FAX (866) 557-8706**, email to **GrifolsCallCenter@snow-companies.com**, or mail hard copy to:
Hypermunes Patient Assistance Program, PO Box 5428, Williamsburg, VA 23188

Please see Important Safety Information about Hypermunes on last page and refer to accompanying full Prescribing Information for complete prescribing details.

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PHYSICIAN INFORMATION

I represent that the information contained in this application is complete and accurate. I verify that, to the best of my knowledge, this patient has no prescription insurance coverage for the product prescribed, including all public programs, and the patient has insufficient financial resources to pay for the prescribed medication. I confirm that the patient prescription is for on-label use. I understand Grifols reserves the right to modify or terminate this program at any time. Furthermore, my signature certifies that these goods will not be sold or offered for sale, trade, or barter and will not be returned for credit. I understand that Grifols reserves the right to recall the product, if necessary.

Prescribing Physician: _____ Physician Phone: _____

State Where Licensed: _____ State License #: _____

DEA #: _____ NPI #:_____ Facility Name: _____

Facility Address:_____ Facility City: _____

Facility State: _____ Facility Zip Code: _____

PRODUCT INFORMATION

Product Administration Date*: _____ Dose Requested or Administered (total IUs): _____

Postexposure Prophylaxis For: Rabies ☐ Tetanus ☐ Hepatitis B ☐ Diagnosis Code: _____

Physician Signature _____ Date_____

* This application must be received no later than 30 days from Product Administration Date.

Patients applying for assistance through the Hypermunes Patient Assistance Program (PAP) must meet the following criteria in order to be eligible for assistance:

- Earn an annual gross income of 250% of the Federal Poverty Level (FPL) or less. If the annual gross income exceeds 250% of FPL, PAP denial will be issued
- Patients must be uninsured in order to be eligible for product assistance
- Documentation of proof of income
- Diagnosis and dosing must be consistent with FDA approved label
- Must be a US citizen or resident and must physically reside in the US or US territory, Puerto Rico or other US territories
- Under the care of a US licensed prescriber with an established practice located in the US
- Documentation of proof of residency will not routinely be required but may be requested at any time by the program through an audit (ie, copy of current valid driver's license or recent utility bill)
- Patient will receive 1 dose as prescribed
- Federally funded patients are not eligible to receive assistance through the PAP. This includes – but is not limited to: Medicare, Medicaid (including spend downs), Tricare, and VA benefits

The following income documentation from the patient is acceptable:

Copy of W-2 or most recently filed US Income Tax Return (IRS Form 1040, 1040A, 1040EZ, 1040NR, or 1040PR), or

Copy of most recent pay stub plus most recently filed US Income Tax Return, or

Copy of transcript received through submission of IRS 4506-T (request for transcript form is not accepted), or

Copy of most recent Social Security/Disability monthly check, award letter, benefit statement, or 1099, or

Copy of Unemployment Determination Letter

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Important Safety Information for Hypermunes

Important Safety Information for HyperRAB® (rabies immune globulin [human])

HYPERRAB® (rabies immune globulin [human]) is indicated for postexposure prophylaxis, along with rabies vaccine, for all persons suspected of exposure to rabies.

Limitations of Use
Persons who have been previously immunized with rabies vaccine and have a confirmed adequate rabies antibody titer should receive only vaccine.

For unvaccinated persons, the combination of HYPERRAB and vaccine is recommended for both bite and nonbite exposures regardless of the time interval between exposure and initiation of postexposure prophylaxis.

Beyond 7 days (after the first vaccine dose), HYPERRAB is not indicated since an antibody response to vaccine is presumed to have occurred.

Important Safety Information

For infiltration and intramuscular use only.

Severe hypersensitivity reactions may occur with HYPERRAB. Patients with a history of prior systemic allergic reactions to human immunoglobulin preparations are at a greater risk of developing severe hypersensitivity and anaphylactic reactions. Have epinephrine available for treatment of acute allergic symptoms, should they occur.

HYPERRAB is made from human blood and may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob (CJD) agent.

The most common adverse reactions in >5% of subjects during clinical trials were injection-site pain, headache, injection-site nodule, abdominal pain, diarrhea, flatulence, nasal congestion, and oropharyngeal pain.

Do not administer repeated doses of HYPERRAB once vaccine treatment has been initiated as this could prevent the full expression of active immunity expected from the rabies vaccine.

Other antibodies in the HYPERRAB preparation may interfere with the response to live vaccines such as measles, mumps, polio, or rubella. Defer immunization with live vaccines for 4 months after HYPERRAB administration.

Please see accompanying full Prescribing Information for HyperRAB or visit www.hypermunes.com for complete prescribing details.

Important Safety Information for HyperTET® (tetanus immune globulin [human])

HyperTET® (tetanus immune globulin [human]) is indicated for prophylaxis against tetanus following injury in patients whose immunization is incomplete or uncertain.

HyperTET should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperTET should be given only if the expected benefits outweigh the risks. Slight soreness at the site of injection and slight temperature elevation may be noted at times. Sensitization to repeated injections of human immunoglobulin is extremely rare. In the course of routine injections of large numbers of persons with immunoglobulin, there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection. Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after tetanus immune globulin (human) administration.

HyperTET is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.

Please see accompanying full Prescribing Information for HyperTET or visit www.hypermunes.com for complete prescribing details.

Important Safety Information for HyperHEP B® (hepatitis B immune globulin [human])

HyperHEP B® (hepatitis B immune globulin [human]) is indicated for postexposure prophylaxis in the following situations: acute exposure to blood containing HBsAg, perinatal exposure of infants born to HBsAg-positive mothers, sexual exposure to an HBsAg-positive person, and household exposure to persons with acute HBV infection.

HyperHEP B should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Epinephrine should be available.

In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, hepatitis B immune globulin (human) should be given only if the expected benefits outweigh the risks.

Local pain and tenderness at the injection site, urticaria, and angioedema may occur; anaphylactic reactions, although rare, have been reported following the injection of human immunoglobulin preparations. Administration of live virus vaccines (eg, MMR) should be deferred for approximately 3 months after hepatitis B immune globulin (human) administration.

HyperHEP B is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent that can cause disease. There is also the possibility that unknown infectious agents may be present in such products.

Please see accompanying full Prescribing Information for HyperHEP B or visit www.hypermunes.com for complete prescribing details.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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