

Prevention of Rabies in Humans:

Rabies Biologics and Patient Assistance Programs

Rabies Biologics

The Advisory Committee on Immunization Practices (ACIP) Recommendations (https://www.cdc.gov/rabies/resources/acip_recommendations.html) provides information on the two human rabies vaccines and manufacturers, Imovax (Sanofi Pasteur) and RabAvert (Novartis), as well as the two human rabies immune globulin (HRIG) products, Imogam (Sanofi Pasteur) and HyperRabS/D. Since the publication of the 2008 ACIP Recommendations, Grifols has stopped producing HyperRabS/D and has replaced it with a higher concentration product, HyperRab. In addition, a newer HRIG product, KEDRAB, is now available in the U.S.

TABLE 1. Currently available rabies biologics (adapted from the 2008 ACIP recommendations)

Human rabies vaccine	Product name	Manufacturer	Dose	Route	Indications
Human diploid cell vaccine	Imovax® Rabies*	Sanofi Pasteur Phone: 800-822-2463 Website: Imovax® Rabies	1 mL	Intramuscular	Pre-exposure or postexposure†
Purified chick embryo cell vaccine	RabAvert®	Novartis Vaccines and Diagnostics Phone: 800-244-7668 Website: RabAvert®	1 mL	Intramuscular	Pre-exposure or postexposure†
Rabies immune globulin	Imogam® Rabies-HT	Sanofi Pasteur Phone: 800-822-2463 Website: Imogam® Rabies-HT	20 IU/kg	Local§	Postexposure only
	HyperRab™	Grifols Biotherapeutics Bayer Biological Products Phone: 800-243-4153 Website: HyperRab™	20 IU/kg	Local§	Postexposure only
	KEDRAB™	Kedrion Biopharma Website: KEDRAB	20 IU/kg	Local§	Postexposure only

* Imovax rabies I.D., administered intradermally, is no longer available in the United States.

† For postexposure prophylaxis, the vaccine is administered on days 0, 3, 7, 14 in patients who have not been previously vaccinated and on days 0 and 3 in patients who have been previously vaccinated. For pre-exposure prophylaxis, the vaccine is administered on days 0, 7 and 21 or 28.

§ As much of the product as is anatomically feasible should be infiltrated into and around the wound. Any remaining product should be administered intramuscularly in the deltoid or quadriceps (at a location other than that used for vaccine inoculation to minimize potential interference).

TABLE 2. Vaccine distributors include (contact companies directly for information on local distributors):

Name	Address	Phone	Web site
CardinalHealth SPD	305 Tech Park Dr. Suite 113 LaVergne, TN 37086	866-476-1340	https://www.cardinalhealth.com/en.html

<u>ASD Healthcare</u>	3101 Gaylord Parkway Frisco, TX 75034	800-746-6273	https://www.asdhealthcare.com
<u>FFF Enterprises, Inc.</u>	41093 County Center Dr. Temecula, CA 92591	800-843-7477	www.fffenterprises.com
<u>McKesson Plasma & Biologics</u>	401 Mason Road La Vergne, TN 37086	877-625-2566	https://www.mckesson.com/

Disclaimer: N.C. DHHS does not endorse any particular company.

Health care providers must report adverse vaccine reactions through the national vaccine safety surveillance program, VAERS (Vaccine Adverse Event Reporting System), at <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>, or by calling 1-800-822-7967. VAERS is co-sponsored by the CDC and the FDA.

Patient Assistance Programs (PAPs)

There may be a need for financial assistance among some patients who are assessed as exposed to rabies and are recommended to receive rabies post-exposure prophylaxis (PEP). These patients may not be eligible for state or federal medical assistance.

It is very important to realize that the eligibility requirements for assistance among PAPs are not uniform; some PAPs may have criteria that are more restrictive than others. An example is the level of income that is relative to the Federal Poverty Level (FPL); guidelines can vary from 100% to 300%.

1. Hospital Charity Care

First determine if the patient qualifies for hospital charity care. The policy for each hospital is located at <https://www.ncha.org/community-benefit/>.

2. Manufacturer's Patient assistance programs

Next determine if the patient is eligible for vaccine manufacturer patient assistance programs. Both rabies vaccine manufacturers have patient assistance programs that provide biologics to qualifying underinsured or uninsured patients.

- **Sanofi Pasteur's Patient Assistance Program** (providing Imogam® Rabies HT and Imovax® IM) An application form and information about the program can be found at: [Sanofi Patient Connection](#) or by telephone at 1-888-847-4877.
- **Novartis Pharmaceuticals Patient Assistance Program** (providing RabAvert®) is managed through RX for Hope and can be accessed at <https://www.rxhope.com/PAP/info/PAPInfo.aspx> or by telephone at 1-800-589-0837.
- **Grifols Patient Assistance Program** (providing HyperRab™) <https://www.hypermunes.com/en/hcp/hyperrab-rabies> or call 833-504-9983
- Other PAPs include <https://www.rxassist.org/>, <https://www.patientassistance.com/>.

3. NC DPH, State Laboratory of Public Health Free Rabies Vaccine Program

The State Laboratory Public Health has a limited supply of rabies biologics (both rabies vaccine and HRIG) on hand through the NC Free Rabies Vaccine or 'Indigent' program.

There is limited funding for this program, therefore, all other sources of patient assistance should be explored prior to requesting biologics through the state program. The criteria for eligibility are 1.) the patient is a NC resident, 2.) the products are recommended by a licensed physician in NC, and 3) the patients is within 100% of the federal poverty level that fiscal year, has no insurance that will pay for PEP and is not eligible for state assistance (Medicaid); 4.) the affidavit must be notarized.

The local health departments are the points of contact and clearing house. Products can only be sent out to LHDs Monday through Thursday to arrive at the LHD during the work week. An affidavit must be completed for each patient that qualifies and returned, along with the invoice, to the SLPH to the address on the affidavit. The [Affidavit for Indigent Status](https://epi.dph.ncdhhs.gov/cd/rabies/docs/AffidavitFreePEP.pdf) can be found here: <https://epi.dph.ncdhhs.gov/cd/rabies/docs/AffidavitFreePEP.pdf>. The invoice is in lieu of payment. Only product is provided; there is no reimbursement for all other health provider services.

Call the Communicable Diseases Branch (919-733-3419) to arrange for shipping of the biologics.