

New Clotting Factors in Development



Ask your doctor to let you know when new clotting factors are approved and if they are right for you.

In this edition of CareConnections, we will update you on the status of some forms of clotting factors that are being studied for hemophilia A and B. Some of these therapies may be experimental and some may have already been approved by the FDA (U.S. Food and Drug Administration).

Factor VIII - for the treatment and/or prevention of Hemophilia A.

- ▶ **Eloctate** - First long-acting Factor VIII that widens the time between preventative doses. New dosing will be every 3 to 5 days, instead of every other day. **FDA approved June 2014.**
- ▶ **N8-GP (turoctocog alfa pegol)** - Long-acting form of Novoeight that reduces the number of preventative doses each week. Provides longer protection from bleeds. **Trial is in Phase 3 (last stage of testing).**

Factor IX - for the treatment and/or prevention of Hemophilia B.

- ▶ **Alprolix™** - First long-acting Factor IX that widens the time between preventative doses. New dosing will be every 7 to 10 days, unlike current dosing of 2 or more times per week. **FDA approved March 2014.**
- ▶ **N9-GP (NN7999)** - Long-acting Factor IX made to reduce the number of preventative doses. Provides longer protection from bleeds. **Trial is in Phase 3.**

Recombinant Factor VIIa - for the treatment of Hemophilia A or B with Inhibitors.

- ▶ **LR769** - First Factor VIIa treatment option in 15 years. **Trial is in Phase 3.**

Ask your doctor, pharmacist, or Health Management Nurse to let you know when these new clotting factors are approved and if any of them may be right for you.

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Phase 3 Clinical Trial

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Many hemophilia treatments are being studied right now. So, let's talk about why clinical trials are important and what a Phase 3 trial means.

Clinical trials help answer these questions about treatments:

- ▶ What does the treatment do to the body?
- ▶ Does it treat, prevent, or manage a medical condition or problem?
- ▶ How well does it work?
- ▶ What are the side effects?
- ▶ Who can it be used in?
- ▶ How often does it need to be taken?
- ▶ What is the right dose?

Phase 3 trials are done in large groups of people with the condition. In this case, **hemophilia A or B**. Researchers may compare the trial medicine with a treatment commonly used for the condition. Or the trial medicine may be compared to a placebo. A placebo looks the same and is given the same way as the trial medicine. But, it does not have any active medicine in it. In some cases, a Phase 3 trial may test different doses. Or a trial could study how the trial medicine works with other treatments.

If a Phase 3 trial is successful, then the FDA will review all of the information and decide whether the medicine will be approved for use.



Some of the medicines/treatments talked about in this newsletter may not be available for use by the public or may not be covered by your health plan. Talk to your doctor or Health Management Nurse if you have questions. Remember to call your health plan's customer service department to find out what medicines are covered.

This *CareConnections* newsletter was reviewed for medical accuracy by Andrew Krueger, MD, FACP.

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