



Briefing Note 2018/038

Date 09/08/2018

Event: Updated Restrictions on use of Varicella Zoster Immunoglobulin (VZIG) during supply shortage

Notified by	Immunisation and Countermeasures Division, National Infection Service
Authorised by	Mary Ramsay, Mike Gent
Contact	Gayatri Amirthalingam, Kevin Brown
PHE NIRP Level	N/A
Incident Lead	N/A

Background and Interpretation

Chicken pox (varicella) infection in neonates, immunosuppressed individuals and pregnant women can result in severe and even life-threatening varicella disease. To attenuate disease and reduce the risk of complications such as pneumonitis, rather than to prevent infection in these at risk individuals, post-exposure prophylaxis (PEP) with varicella-zoster specific immunoglobulin (VZIG) is recommended according to [national guidelines](#).¹

In response to a severe supply shortage of VZIG, the Immunisation Division at PHE issued a [briefing note](#)² on 6th July 2018 restricting the use of VZIG in pregnancy, to susceptible women exposed in the first 20 weeks of pregnancy, with immediate effect. For women exposed after 20 weeks, PEP with oral aciclovir (800mg four times a day from day 7 to day 14 after exposure) was to be considered. At the time, guidance on the use of VZIG for immunosuppressed individuals and neonates remained unchanged.

Since issuing the briefing note, it has become evident that the supply situation is unlikely to improve in the short term. As a result, a PHE convened expert working group has reviewed the evidence on the safety and efficacy of antiviral agents as post-exposure prophylaxis (PEP) and have advised on the prioritisation of available stock. In order to retain stock for the most vulnerable groups, the expert group recommends:

- Continue restriction of VZIG for pregnant women to those exposed in the first 20 weeks of pregnancy
- Recommend (as opposed to consider) the use of antivirals (aciclovir or valaciclovir) from day 7 to day 14 after exposure for susceptible pregnant women who are not eligible for VZIG
- No longer issue VZIG for immunosuppressed patients and recommend the use of prophylactic antivirals (aciclovir or valaciclovir), unless oral antivirals cannot be given
- No changes to the guidelines on the use of VZIG to susceptible neonates
- Consider withdrawing VZIG stock most of the issuing centres so that all remaining VZIG can be held centrally and prioritised for those at greatest risk

These updated restrictions on the use of VZIG are now available at <https://www.gov.uk/government/publications/immunoglobulin-when-to-use> and are being implemented with immediate effect. Guidance on the rationale for these changes and the appropriate dosage regimens for oral antiviral agents (aciclovir / valaciclovir) in pregnant women (exposed after 20 weeks) and immunosuppressed individuals (all ages) are included. PHE is keeping the situation under constant review. This guidance will remain in place until further notice.

Current restrictions in England for use of VZIG

- **Pregnant Women**

From 6th July 2018, VZIG should only be issued to VZ antibody negative pregnant contacts exposed in the first 20 weeks of pregnancy i.e. up to and including 20+0 weeks.



For susceptible women exposed after 20 weeks i.e. from 20+1 weeks to delivery, oral aciclovir at 800mg four times a day from days 7 to 14 after exposure is recommended. Valaciclovir 1000mg three times a day from days 7 to 14 after exposure can be used as a suitable alternative.

- **Immunosuppressed individuals**

From 9th August 2018, VZIG will no longer be issued to susceptible immunosuppressed contacts following a significant exposure. Oral aciclovir or valaciclovir is recommended for these individuals unless there are significant concerns of renal toxicity or malabsorption. For such individuals VZIG will be considered as part of the risk assessment. Details on the recommended doses of aciclovir and valaciclovir can be found in the updated guidelines

- **Neonates**

There are no changes to the guidance¹ for neonates

Off label use of aciclovir and valaciclovir

Although oral aciclovir and valaciclovir are not licensed for use in pregnancy or for PEP, their use in the treatment of chickenpox is well established. Clinicians are able to prescribe medicines outside the terms of the licence (i.e. 'off-label') when this is in the best interest of the patient on the basis of available evidence. Further advice on off-label prescribing is on the MHRA website.

<https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities#prescribing-in-a-patients-best-interests>

When current practice supports the use a medicine outside the terms of its licence, the MHRA advise that it may not be necessary to draw attention to this when seeking consent from patients. However, it is good practice to give as much information as patients or carers require or which they may see as relevant.

Pregnant women and Immunosuppressed individuals presenting with chickenpox

If the patient develops chickenpox despite prophylaxis, a treatment dose of antivirals should be started.

Implications and Recommendations for PHE Centres

Health Protection Teams (HPTs) often undertake the risk assessment for VZIG and are asked to note the current restrictions for VZIG in pregnant and immunosuppressed patients and the recommendation for antiviral prophylaxis.

Health Protection Teams should facilitate the cascade of this briefing note to their hospitals (particularly local maternity units, paediatric, infectious disease, oncology, haematology and microbiology departments) and General Practitioners through local systems, to ensure they are aware of the latest advice.

As the stocks of VZIG are withdrawn from the issuing centres, HPTs should be prepared to advise local physicians on how to order VZIG through the [Rabies and Immunoglobulin team](#) at Colindale.

Implications and recommendations for PHE sites and services

The Specialist microbiology network often support the risk assessment and undertake recommended laboratory investigation of high risk contacts exposed to varicella. The network are asked to note the current restrictions on VZIG supplies, the indications for VZIG use in pregnant and immunosuppressed patients and the recommendation for antiviral prophylaxis.

Lead Public Health microbiologists are requested to forward this briefing note to their local NHS Laboratories / microbiologists who may be involved in urgent requests for VZ IgG testing and the risk assessment for high risk contacts exposed to varicella.

As the stocks of VZIG are withdrawn from the issuing centres, public health microbiologists should be reminded of the criteria for issuing VZIG, including the requirement for quantitative testing as in the national guidelines, and be prepared to advise local physicians of how to order VZIG through the [Rabies and Immunoglobulin team](#) at Colindale.



Implications and recommendations for local authorities

N/A

References/ Sources of information

1. PHE Guidance for issuing varicella zoster immunoglobulin. August 2017. Available at <https://www.gov.uk/government/collections/chickenpox-public-health-management-and-guidance>
 2. PHE Briefing Note 2018/032. Issued 06/07/2018. Available at: <http://phenet.phe.gov.uk/Our-Organisation/Health-protection-briefings/Briefing%20notes%202018/Guidance-on-use-of-Varicella-Zoster-Immunoglobulin-VZIG-during-supply-shortage.pdf>
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