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IMMEDIATE MESSAGE TO:

Medical Directors NHS Boards
Directors of Pharmacy

30 July 2024

Dear Healthcare Professional,

NATIONAL PATIENT SAFETY ALERT/2024/009/DHSC SHORTAGE OF HUMAN ALBUMIN 4.5% AND 5% DOSE VIALS

The supply disruption is caused by a combination of increased global demand for Human Albumin resulting in one supplier being unable to bring in sufficient stock and a sustained overall increase in demand for the product.

There will be limited stock of Human Albumin from July 2024 until at least December 2024. Resolution date for a resumption of full market coverage is still to be confirmed.

This National Patient Safety Alert provides background and clinical information and actions for providers for onward transmission as below :

Please could all Directors of Pharmacy please forward this alert to:-

- Chief Pharmacists
- Hospital Pharmacists
- Community Pharmacists

Please could Medical Directors arrange to forward this alert on to:-

- General Practitoners
- Dispensing Doctors
- Relevant Clinics Private Healthcare providers

Thank you for your co-operation.
Yours sincerely

IRENE FAZAKERLEY
Medicines Policy Team

National Patient Safety Alert

Department of Health & Social Care

NHS England

Shortage of Human Albumin 4.5% and 5% dose vials

Date of issue:	30-Jul-24	Reference no:	NatPSA/2024/009/DHSC

This alert is for action by: All organisations involved in prescribing, dispensing, and administering Human Albumin 4.5% and 5%.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in acute medicine, critical care, neurology, hepatology, gastroenterology, cardiac surgery renal medicine, pathology, pharmacy and paediatric services.

Explanation of identified safety issue:

There will be limited stock of Human Albumin from July 2024 until at least December 2024. Resolution date for a resumption of full market coverage is still to be confirmed.

The supply disruption is caused by a combination of increased global demand for Human Albumin resulting in one supplier being unable to bring in sufficient stock and a sustained overall increase in demand for the product.

Volumes of Human Albumin 20% remain available but cannot support an uplift to meet the additional demand from the 4.5% and 5% preparations.

Human Albumin is licensed for restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. However, in practice it is used extensively for

- Plasma expansion after paracentesis
- Plasma exchange in neuroinflammatory crises
- Treatment of hepatorenal failure in association with terlipressin

Remaining volumes of Human Albumin should be prioritised for patients that clinical leads have indicated are critical.

Actions required

Actions to be completed as soon as possible and not later than 07 August 2024

All providers MUST:

1. Take immediate action to preserve stock of Human Albumin for patients for whom this treatment is critical.
2. Ensure stock of Human Albumin is ringfenced for;
   a. major aortic surgery and cardiac transplant.
   b. paediatric patients - used peri-liver transplant to manage protein loss associated with high drain losses, cirrhotic children hospitalised with significant portal hypertension and ascites, nephrotic range proteinuria, extracorporeal therapies and gene and cell therapies.
   c. Plasma exchange for renal vasculitis.
3. Ensure clinical guidance is amended where appropriate to ensure Human Albumin is not being used for indications with limited data to support its use (see clinical information).
4. If volumes of Human Albumin held at trust level are deemed surplus to anticipated demand, inform your regional pharmacy procurement specialist who may be able to facilitate mutual aid to another hospital.
5. If anticipated demand of Human Albumin for critical patients is higher than you are able to access from your contracted supplier;
   a. contact your regional pharmacy procurement specialist who may be able support with mutual aid.
   b. utilise alternative appropriate clinical treatments. (See clinical information).
6. Consider the use of intravenous immunoglobulin in place of Albumin and plasma exchange for neurological conditions such as Myasthenia Gravis and Guillain-Barre syndrome.
7. Ensure Albumin is not used in standard fluid therapy

Additional information

Clinical information

Human Albumin should not be commenced in the following instances

- **Neurocritical care**: There is good trial data to suggest that Human Albumin should not be used in traumatic brain injury where it may be associated with a worse outcome. UK and international guidance on the management of traumatic brain injury, subarachnoid haemorrhage, and stroke does not support the use of albumin.
- **Trauma and resuscitation**: Albumin should not be used in the resuscitation of patients following trauma or haemorrhage, this is supported by UK and international guidance.
- **Recovery from critical illness**: There is little evidence to support use of Human Albumin in patients who are hypoalbuminemic following critical illness associated with trauma. Trial data suggests that there is no benefit in terms of ventilator free days, ICU length of stay, and hospital length of stay.
- **Hepatology and Gastroenterology**
  - Human Albumin for long term intermittent administration to people with cirrhotic ascites or simple fluid resuscitation in people with cirrhosis/ascites, is not recommended.
  - Human Albumin to correct hypoalbuminaemia in cirrhosis does not improve outcomes and is not recommended.
  - Human Albumin for the prevention of PPCD (post-paracentesis circulatory disturbance, effectively hyponatraemia and renal impairment) following large volume paracentesis (LVP) in the treatment of ascites in cirrhosis if less than 5 litres of ascitic fluid is drained is not recommended unless a high risk patient.

Human Albumin should be considered in the following instances

- **Paediatrics -Renal**: use in nephrotic range proteinuria with refractory oedema and evidence of hypovolaemia with acute kidney injury.
- **Paediatrics- Liver:** use peri-transplant to manage protein loss associated with high drain losses and in cirrhotic children hospitalised with significant portal hypertension and ascites.

Fresh Frozen plasma is not a suitable alternative colloid for either indication as it masks changes in INR essential for monitoring progress of liver dysfunction

- **Hepatology and Gastroenterology**
  - Adjunct to antibiotics in the treatment of SBP (spontaneous bacterial peritonitis) in people with cirrhotic ascites and the prevention of PPCD (post-paracentesis circulatory disturbance, following large volume paracentesis (LVP) in the treatment of ascites in cirrhosis > 5 litres of ascites is drained in ambulatory patients. The evidence-supported dose is to give 8g of intravenous albumin per litre of ascites fluid drained. see BSG guidance on Ascites
  - For the treatment of hepatorenal syndrome (HRS) in association with terlipressin (providing right heart function is normal)
- **Critical Care**: Use in unresponsive septic shock
- **Neurology**: Use with plasma exchange in neuroinflammatory crise for conditions such as:
  - Myasthenia Gravis / Guillain-Barre syndrome / Autoimmune encephalitis / Neuromyelitis optica

For autoimmune encephalitis and neuromyelitis optic, plasma exchange is the preferred treatment due to perceived / theoretical efficacy issues (e.g. prevalence of IgG4 autoantibodies)

Stakeholder engagement:
The following stakeholders have been engaged in the management and consulted in the drafting of this alert: NHS Specialist Pharmacy Service Medicine Advice, Medicine Shortage Response Group, NHS England, National Clinical Directors for Critical care, Blood and infection and Internal Medicine , National speciality advisors for hepatobiliary and pancreas and paediatric renal services , clinicians with specialist interest in Paediatrics/ Neurology/ Cardiac surgery and national patient safety team, Medicine and Healthcare products Regulatory Agency and the Devolved Governments.

Advice for Central Alerting System (CAS) officers and risk managers
This is a safety critical and straightforward National Patient Safety Alert. In response to CHT/2023/0032 your organisation should have developed new processes to ensure appropriate oversight and co-ordination of all National Patient Safety Alerts. CAS officers should send this Alert to the nominated executive lead in their new process to coordinate implementation of safety critical and complex National Patient Safety Alerts, copying in the leads identified on page 1.