TM08-04.006 Irradiated Blood Products Policy

APPLICABILITY

Compliance with this document is required by all Alberta Precision Laboratories Ltd. (APL) employees, medical staff, students, and other persons acting on behalf of APL (including contracted service providers as necessary).

PURPOSE

This policy provides direction for the appropriate selection of irradiated blood products.

BACKGROUND

Irradiation of blood products is recommended to reduce the risk of Transfusion Associated Graft Versus Host Disease (TA-GVHD) in immunocompromised recipients.

Irradiated blood products are more costly to provide than non-irradiated products. In addition, irradiation of red blood cells (RBC) impacts the quality and integrity of the cells and reduces the shelf life of RBC units. Therefore, transfusion of irradiated RBC should be limited to patients with a clinical need.

DEFINITIONS

Cellular Therapy Product	A somatic cell-based product that is procured from a donor and intended for processing and administration. E.g. stem cell transplant (SCT) or bone marrow transplant (BMT)
Irradiation	Treatment of a blood product using electromagnetic radiation. This inflicts irreparable DNA damage to T-lymphocytes and any nucleated cells and prevents them from replicating, thereby preventing TA-GVHD.
Transfusion Associated Graft Versus Host Disease	A rare, usually fatal complication of transfusion resulting from the transfusion of donor T-lymphocytes into a recipient whose immune system is not capable of eliminating them. These donor lymphocytes attack and cause damage to recipient tissues. Patients at highest risk include those who are severely immunocompromised, and those who receive blood products from a donor with similar human leukocyte antigen (HLA) alleles (e.g. directed donations from family members, HLA-matched platelets)
Transfusion Medicine Physician	A physician or pathologist with responsibility for Transfusion Medicine in their sector or zone.

RESPONSIBILITY

The patient's Most Responsible Health Practitioner (MRHP) and health care providers on the patient care units are responsible for:

- Identifying patients who require irradiated blood products.
- Notifying Transfusion Medicine (TM) of the requirement for irradiated blood products.
- Notifying the Cellular Therapy Laboratory of the requirement for irradiated CTP after consulting with the CTL Medical Director/CTL Director
- Notifying TM when irradiated cellular blood products are no longer required.
- Informing the patient of their need for irradiated blood products.

TM Physicians are responsible for:

- Reviewing requests for irradiated blood products that fall outside of recommended indications.

TM personnel are responsible for:

- Meeting the requirements for the provision of irradiated blood products.
- Appropriately recording blood products requirements when notified by physician and patient care units.
- Monitoring the utilization of irradiated blood products for appropriateness.
- Updating patient's history or registry file in the LIS with irradiation requirements.

AHS Zone Clinical Department Heads are responsible for:

- Communicating and educating clinical colleagues on the appropriate use of irradiated blood products.

POLICY

APL TM shall provide irradiated blood products according to the recommendations outlined below.

Orders for irradiated blood products that fall outside of the indications listed in the tables below must be assessed by a TM physician or Cellular Therapy Medical Lead on a case by case basis.

The following tables are based on international guidelines, and represents a minimum standard. TM and individual physicians may choose to provide irradiated products for additional patient groups based on transfusion committee / TM physician recommendations.

Included in this Policy is:

1. Products Requiring Irradiation

TM shall ensure the following blood products are irradiated, regardless of the immune status of the recipient:

- All HLA-selected/matched platelets.
- All granulocytes.
- Any products where the donor is a first- or second-degree relative of the patient (directed donation).
- RBC and platelets to be transfused to a patient identified to be at risk of transfusion-associated graft-vs-host disease (TA-GVHD).
- Cellular Therapy Products (CTP) for infusion into a recipient with relapsed or refractory disease to induce graft vs leukemia effect but prevent GVHD.

Note: It is not necessary to irradiate fresh frozen plasma, cryoprecipitate, pathogen inactivated blood products, or fractionated plasma products.

Irradiated Product Availability

- Not all hospitals in Alberta have the ability to irradiate on-site, or stock irradiated products in regular inventory.
- In the event of emergency transfusion, when irradiated RBC are indicated but not available, RBC that have been stored for more than 14 days shall be provided if possible.
- Prolonged storage of pre-irradiated units is associated with high potassium levels, in vitro hemolysis, and decreased post-transfusion recovery. Therefore, TM shall avoid maintaining large inventories of irradiated RBC which may result in potentially harmful transfusion of irradiated RBC to patients who do not require them.

2. Contraindications

Due to the risk of increased potassium and in vitro hemolysis in irradiated RBC units, irradiated RBC should not be issued to the following patient types unless the patient has a specific clinical indication requiring irradiated products:

- Patients with a history of renal disease
- Patients with elevated potassium or creatinine
- Patients at high risk of hyperkalemic arrest
- Patients on dialysis
- Patient in cardiac intensive care units
- Patient known to be using rapid infusers (e.g. trauma or massive hemorrhage)

When inventory pressures require the use of irradiated RBC for patients who do not have a patient attribute necessitating irradiation, TM will attempt to limit these units from being issued to the above patient populations. This exclusion may be based on the location of the patient (e.g. dialysis unit) or clinical indication that is readily available or included with the order.

If inventory pressures require irradiated RBC to be given to the above patient populations, consult the TM physician. (e.g. O Negative inventory is irradiated and an MHP is activated).

3. Patients Approved for Irradiated Blood Products

Table 1: Fetal and Neonatal Patients

- Neonates less than 14 days old should receive units irradiated within the last 24 hours. If these are not available, then non-irradiated units greater than 14 days old should be provided.

Patient	Scenario	Approval Duration
Fetus	Intra-uterine transfusion (IUT)	N/A
Neonate	All	Up to 14 days of age (regardless of gestational age or low birthweight)
Neonate	Exchange transfusion	Up to 4 months of age
Neonate	Previously received IUT	Until 6 months after expected delivery date (40 weeks gestation)
Neonate	Congenital T cell immunodeficiency suspected or confirmed	Until congenital T cell immunodeficiency is excluded* Indefinitely if confirmed.
Neonate	Complex cardiac malformation / Chromosome 22q11 deletion /	Until 22q11 deletion is excluded* Indefinitely if confirmed.

*The presence of a congenital cardiac abnormality identified in a neonate or infant may raise the suspicion of chromosome 22q11 deletion syndrome, commonly associated with a congenital T cell immunodeficiency.

Since newborn screening in the province of Alberta identifies patients with this risk within the first two weeks of life the provision of irradiated products on suspicion secondary to cardiac abnormality will be restricted to patients from outside of Alberta until testing is completed. Irradiated products will be provided until T lymphocyte immunodeficiency syndrome has been excluded.

Cardiac abnormalities most frequently associated with chromosome 22q11 deletions include: Tetralogy of Fallot, ventricular septal defect, interrupted aortic arch, combined pulmonary atresia and ventricular septal defect, and truncus arteriosus.

There is no need to irradiate red cells or platelets for infants undergoing cardiac surgery unless clinical or laboratory features suggest a coexisting T lymphocyte immunodeficiency syndrome.

Table 2: Specific Diagnoses and Treatments

Diagnosis / Treatment		Approval Duration
Hodgkin's Disease (Hodgkin lymphoma)		Indefinitely
Suspected or confirmed (T cell) congenital immune deficiency (i.e. Wiskott-Aldrich, Di Georges, SCID)		Indefinitely
Patients treated with purine analogs	Fludarabine, cladribine, deoxycoformycin	Indefinitely
	Other purine analogues (e.g. clofarabine)*	No defined duration** Physician to review annually**
Patients treated with: ▪ Bendamustine, alemtuzumab (anti-CD52) ▪ Anti-thymocyte globulin (ATG) for severe aplastic anemia. ▪ Other immunosuppressive agents not listed*		No defined duration** Physician to review annually**
*This is not an exclusive list of diagnoses or immunosuppressive agents that may warrant provision of irradiated products. Consult with a TM physician is recommended. **The decision to provide irradiated blood for patients on immunosuppressive agents should be made with consideration given to perceived risks and benefits of irradiated blood transfusion, the availability of the irradiated products, and the immunosuppressive potency of the agent. Discussion between the patient's most responsible physician and a TM physician is advised.		

Note: Consult the AHS Parenteral Monographs for drug information, including trade vs. generic names.

Table 3: Transplant Recipients and Donors

Patient / Donor	Approval Begins	Approval Duration
Allogeneic bone marrow or stem cell transplant recipient	From start of conditioning chemotherapy	Indefinitely
Donors (including autologous) of bone marrow and peripheral blood stem cells receiving allogenic transfusions	7 days prior to harvest	Until harvest of bone marrow/stem cells
Patients with transplant associated graft-versus-host disease (GVHD)	At diagnosis	Indefinitely
Autologous bone marrow or stem cell transplant recipient	From start of conditioning chemotherapy	1-year post-transplant

REFERENCES

Clinical Guide to Transfusion, Chapter 15 Irradiated, Washed, and CMV Seronegative Blood Components. Canadian Blood Services On-line Edition, 2 March 2021. https://professionaleducation.blood.ca

Recommendations for use of irradiated blood components in Canada, National Advisory Committee on Blood and Blood Products, A MAN and CCNMT Collaborative Initiative: 2018-05-14. www.nacblood.ca

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Government of Canada. Health Canada. Health Products and Food Branch. *Blood Regulations,* CRC, SOR/2013-178 (2015). Current to 2021-09-11