

Fludarabine/Busulfan (FluBu4) – with post-transplant cycloPHOSphamide Therapy (PTCy)

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Myeloablative conditioning with fludarabine and busulfan for matched and mismatched donor with peripheral blood stem cells (PBSC)	C81 - C86, C90 - C95	00910a	N/A

* This applies to post 2012 indications

TREATMENT:

- Conditioning chemotherapy is administered over 5 days
- Stem cells are infused on day 0
- Two doses of cycloPHOSphamide are administered post stem cell transplant
- Facilities to treat anaphylaxis must be present when conditioning therapy and stem cells are administered

Day	Drug	Dose	Route	Diluent & Rate
-6, -5, -4, -3, -2 (must be administered at least 48 hours before stem cell infusion)	ⁱ Fludarabine ^a	30mg/m ²	IV infusion	100mL NaCl 0.9% over 30 minutes
-6, -5, -4, -3 (Start at 10:30)*	ⁱ Busulfan ^{b, c}	0.8mg/kg	IV infusion	(See note ^d) mL NaCl 0.9% over 2 hours
-6, -5, -4, -3 (Start at 16:30)*	ⁱ Busulfan	0.8mg/kg	IV infusion	(See note ^d) mL NaCl 0.9% over 2 hours
-6, -5, -4, -3 (Start at 22.30)*	ⁱ Busulfan	0.8mg/kg	IV infusion	(See note ^d) mL NaCl 0.9% over 2 hours
-5, -4, -3, -2 (Start at 04:00)*	ⁱ Busulfan	0.8mg/kg	IV infusion	(See note ^d) mL NaCl 0.9% over 2 hours
NB: IV busulfan expires after 15 hours, infusion must begin at time specified				
0 (must not begin until at least 48 hours after fludarabine infusion)	Stem Cell Re-infusion			
+3, +4 (Start at 09.30)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion
+3, +4 (Start at 10:00)* (first dose between 60 and 72 hours after the start of the PBSC infusion)	cycloPHOSphamide	50mg/kg (see Dose Modifications section for dosing in obesity)	IV infusion	1000mL NaCl 0.9% over 3 hours
+3, +4 (Start at 13:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion
+3, +4 (Start at 16:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion
+3, +4 (Start at 19:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion

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+3, +4 (Start at 22:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion
+4, +5 (Start at 02:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast-flowing NaCl 0.9% infusion
+4, +5 (Start at 06:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast flowing NaCl 0.9% infusion
+5 (Start at 10:00)*	Mesna	20mg/kg	Slow IV push	Into side arm of a fast flowing NaCl 0.9% infusion
Dose rounding: Fludarabine doses ≤50mg to the nearest 2.5mg and doses >50mg to the nearest 5mg Busulfan to the nearest 1.2mg if <60mg, to nearest 6mg if >60mg Oral busulfan is available as 2mg tablets and 25mg capsules, (emergency stock on Denis Burkitt Ward) Mesna to the nearest 100mg cycloPHOSphamide to the nearest 20mg				
^a All patients who have received fludarabine should receive irradiated blood products (lifetime recommendation) Fludarabine must be administered at least 48 hours before stem cell infusion				
^b IV busulfan may be replaced with oral busulfan at the discretion of the haematology consultant. An oral dose of 1mg/kg is equivalent to the 0.8mg/kg IV dose. The dosing schedule for oral busulfan is 06:00, 12:00, 18:00, 23:59				
^c If a problem with an infusion bag (i.e. leaking bag, short expiry) is discovered outside of 8.30am-5pm, an oral dose of busulfan 1mg/kg equivalent to the intravenous dose will be available from the MDA press on Denis Burkitt Ward This can only be used after discussion with a haematology consultant and must be prescribed by haematology registrar or consultant on a chemotherapy prescription/NCIS				
^d Calculation of busulfan infusion solution: [(busulfan dose (mg) divided by 6) x 10] [to the nearest 10ml] NaCl 0.9% - concentration to be as close to 0.5mg/mL as possible.				
*denotes recommended administration time				

Note: Administration volumes and fluids have been standardised to facilitate electronic prescribing system builds.

ELIGIBILITY:

- Indications as above
- Medical assessment as per SJH BMT assessment

EXCLUSIONS:

- Hypersensitivity to fludarabine, busulfan, cycloPHOSphamide or any of the excipients

PRESCRIPTIVE AUTHORITY:

- The treatment plan must be initiated by a Haematology Consultant working in the area of stem cell transplantation in a unit suitable for carrying out this treatment

TESTS:

- Baseline and regular tests in accordance with SJH Haematopoietic Stem Cell Transplant workup protocols

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

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DOSE MODIFICATIONS:

Any dose modification should be discussed with a Haematology Consultant

Chemotherapy dosing in obese adult patients:

- For patients with a BMI > 30kg/m² please refer to 'Chemotherapy Dosing in Obese Adult Stem Cell Transplant Recipients – Guidelines' for guidance on individual drug dosing as per SJH policy available on the SJH intranet
- The cycloPHOSphamide dose is to be calculated using Ideal Body Weight. However, if Actual Body Weight < Ideal Body Weight, use Actual Body Weight

Table 1: Calculation of different dosing methods in obesity

IBW	Male	IBW = 50kg + 2.3kg for every 2.54 cm above 152.4 cm
	Female	IBW = 45.5kg + 2.3kg for every 2.54 cm above 152.4 cm
ABW 25	IBW + 0.25 x (TBW – IBW)	

Renal and Hepatic Impairment:

- Dose modifications are generally not undertaken in conditioning regimens
- Discuss with the consultant if hepatic impairment or if creatinine clearance is <70mL/minute for advice on fludarabine dosing. Guidance to inform this discussion available at: U:\PHARMCOMP\Clinical\haematology\Haematology Drugs\Fludarabine
- Consult the following resources to inform any renal or hepatic dose modification discussions:
 - Summary of product characteristics (SPC) available at <http://www.hpra.ie>
 - Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: <https://pubmed.ncbi.nlm.nih.gov/37269847/>

SUPPORTIVE CARE:

No systemic immunosuppressive agents, such as corticosteroids, should be given from day 0 until 24 hours after the completion of the post-transplant cycloPHOSphamide (Day +5).

Antiemetics:

Avoid dexAMETHasone as an antiemetic from day -1 to day +5.

Table 2: Recommended SJH Regimen Specific Antiemetics

Prevention of acute emesis			Prevention of delayed emesis		
Drug	Dose	Admin Day	Drug	Dose	Admin Day
Ondansetron	8mg PO/IV TDS	-6 to -3 and +3 to +4	Aprepitant	80mg PO OD	+4, +5, +6
Aprepitant	125mg PO OD	+3			

cycloPHOSphamide hydration and diuresis

Post stem cell infusion:

- Start pre-hydration 4 hours before cycloPHOSphamide begins (usually on day +3). The

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- recommended hydration regimen is 2-3L/m² NaCl 0.9% over 24 hours
- Continue hydration for at least 24 hours after completion of cycloPHOSphamide
- Diuretics may be indicated for positive fluid balance, weight gain or declining urine production (<100mL/m²/hour). Furosemide 20-40mg IV PRN should be prescribed

PREMEDICATIONS:

Busulfan conditioning seizure prophylaxis:

- Phenytoin 600mg STAT orally at midnight the night before busulfan treatment, then 300mg OD PO on day -6 to day -3
 - For patients <20 years, review phenytoin dose with consultant

OR

- Levetiracetam 1000mg STAT PO at midnight the night before busulfan treatment, then BD until 48 hours after last dose of busulfan

OTHER SUPPORTIVE CARE:

Table 3: Recommended SJH regimen specific supportive care

GvHD prophylaxis Refer to signed off BMT assessment form for confirmed choice and target level of immunosuppression	Tacrolimus	Mycophenolate Mofetil
	<ul style="list-style-type: none"> Tacrolimus 0.03mg/kg OD IV over 22 hours from day +5 The equivalent oral dose is: <ul style="list-style-type: none"> Total IV dose, BD PO Target levels: 5-10 nanogram/mL 	<ul style="list-style-type: none"> Mycophenolate mofetil 15mg/kg BD PO/IV from day +5 IV dose is the same as PO given over 2 hours in glucose 5% at a concentration of 6mg/mL Maximum total daily dose not to exceed 3g If renal failure, do not exceed dose of 1g BD No dose adjustment for liver disease Mycophenolate mofetil dosing should be monitored and altered as clinically appropriate. Stop MMF at day +35 unless active GvHD present (discuss with Haematology Consultant)
GvHD and VOD prophylaxis	<ul style="list-style-type: none"> Ursodeoxycholic acid 250mg TDS PO Continue until day +90 	
HSV prophylaxis	<p>All patients should receive the following until CD4 count >200/μL:</p> <ul style="list-style-type: none"> valACiclovir 500mg OD PO <p>or</p> <ul style="list-style-type: none"> Aciclovir 250mg TDS IV (if PO route not appropriate or ANC < 0.5X10⁹/L) <p>Patients with an active herpes infection should receive the following:</p> <ul style="list-style-type: none"> valACiclovir 1g TDS PO <p>or</p> <ul style="list-style-type: none"> Aciclovir 10mg/kg TDS IV (if PO route not appropriate) 	
CMV prophylaxis	<p>Prescribe CMV prophylaxis for all CMV seropositive recipients.</p> <p>Patients receiving CMV prophylaxis with letermovir also require HSV prophylaxis above</p> <ul style="list-style-type: none"> Letermovir 240mg OD PO/IV, as appropriate, starting day +1 if patient is receiving ciclosporin immunosuppression 	

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	<ul style="list-style-type: none"> • Letemovir 480mg OD PO/IV, as appropriate, starting day +1 if patient is receiving tacrolimus immunosuppression • Letemovir PO is first line • Letemovir IV at the same PO dose should be prescribed only where the patient cannot tolerate PO or where there are concerns around absorption • CMV prophylaxis is usually continued until day +100 <p>Patients should bring their oral letemovir supply with them on admission. High tech prescription will have been provided to patient at their counselling appointment pre-admission. Liaise with transplant pharmacist if any supply issues arise</p> <p>When ANC $>1.0 \times 10^9/L$, pre-emptive monitoring (9mL in EDTA [purple tube] (Tuesday and Fridays) should be carried out for CMV reactivation/infection in all patients</p>
Antifungal prophylaxis Refer to signed off BMT assessment form for confirmed choice of antifungal prophylaxis	<p>When ANC $<0.5 \times 10^9/L$ or if patients on high dose steroids:</p> <ul style="list-style-type: none"> • Liposomal amphotericin (Ambisome®) 1mg/kg OD IV Mon/Wed/Fri or • Caspofungin 70mg OD IV Mon/Wed/Fri or • Isavuconazole 200mg OD IV <p>If at higher risk due to prior possible/probable fungal infection:</p> <ul style="list-style-type: none"> • Liposomal amphotericin (Ambisome®) 1mg/kg OD IV or • Caspofungin 70mg OD IV if $>80kg$ or caspofungin 70mg OD IV on day 1 of treatment followed by 50mg OD IV thereafter if $<80kg$ or • Isavuconazole 200mg OD IV
PJP prophylaxis	<p><u>1st line therapy</u></p> <ul style="list-style-type: none"> • Co-trimoxazole 960mg BD PO Mon/Wed/Fri • Commence only on engraftment when ANC $>1.0 \times 10^9/L$ if appropriate <p><u>2nd line therapy (if allergic to co-trimoxazole or contraindicated):</u></p> <p><i>PJP Prophylaxis and T. gondii IgG NEGATIVE</i></p> <ul style="list-style-type: none"> • Pentamidine 300mg nebule and salbutamol 2.5mg nebule pre-pentamidine, every 4 weeks plus • Phenoxymethylpenicillin 333mg BD PO <p>Continue the phenoxymethylpenicillin until patients have been revaccinated and have adequate pneumococcal/haemophilus titres</p> <p><i>PCP Prophylaxis and T gondii IgG POSITIVE</i></p> <ul style="list-style-type: none"> • Atovaquone 750mg BD PO plus • Pyrimethamine 25mg OD PO plus • Folinic acid 15mg OD PO plus • Phenoxymethylpenicillin 333mg BD PO <p>Continue phenoxymethylpenicillin until patients have been revaccinated and have adequate pneumococcal/haemophilus titres</p>

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	Please note: If a patient is to be discharged on atovaquone, pyrimethamine or folinic acid, please contact pharmacy in advance to arrange supply and funding through a community drugs scheme
Mouthcare	<p>Mucositis WHO grade < 2:</p> <ul style="list-style-type: none"> 10mL NaCl 0.9% QDS mouthwash Nystatin 1mL QDS PO (use 15 minutes after NaCl 0.9% mouthwash) <p>Mucositis WHO grade ≥ 2:</p> <ul style="list-style-type: none"> Chlorhexidine digluconate 0.12% 10mL QDS PO Nystatin 1mL QDS PO (use 15 minutes after chlorhexidine digluconate 0.12% mouthwash)
Gastroprotection	<ul style="list-style-type: none"> Lansoprazole 30mg OD PO or Omeprazole 40mg OD PO or Esomeprazole 40mg OD IV (if PO not appropriate)
Folate supplementation	<ul style="list-style-type: none"> Folinic acid 15mg OD IV commenced from day + 2 onwards Switch to folic acid 5mg OD PO when appropriate
Vitamin K supplementation	<p>Beginning on day +2 post stem cell transplant:</p> <ul style="list-style-type: none"> Vitamin K (phytomenadione) 10mg once weekly IV
Prevention of vaginal bleeding	<p>If required for menstruating female patients until platelets > 50 x10⁹/L:</p> <ul style="list-style-type: none"> Norethisterone 5mg TDS PO if >55Kg Norethisterone 5mg BD PO if <55kg
Tumour Lysis Syndrome	<p>Consider allopurinol in active disease pre transplant</p> <ul style="list-style-type: none"> Allopurinol 300mg OD PO for 5-7 days and review
Hepatitis B prophylaxis/treatment	<p>A virology screen is completed as part of transplant workup. Hepatitis B prophylaxis or treatment may be initiated in consultation with a Virology Consultant or Hepatology Consultant if required. Options may include:</p> <ul style="list-style-type: none"> Entecavir 500 micrograms OD PO
Prevention of constipation	<p>Consider laxatives if appropriate e.g.</p> <ul style="list-style-type: none"> Senna 15mg nocte PO while on ondansetron
Antibiotic standing order	<p>Antibiotic standing order should be prescribed for neutropenic sepsis/neutropenic fever based on previous microbiology and renal function:</p> <ul style="list-style-type: none"> Piptazobactam 4.5g QDS IV plus Amikacin* 15mg/kg OD IV <p>*Ciprofloxacin 400mg BD IV may be considered instead of amikacin in cases of renal impairment</p> <p>Refer to Antimicrobial Guidelines for antibiotic choice where a patient is allergic to any of the above</p>
Magnesium and potassium standing order	Magnesium and potassium standing orders should be prescribed for all transplant patients in accordance with stem cell unit practice as indicated on EPMAR
VTE prophylaxis	Consider VTE prophylaxis in accordance with SJH policy
Bone Health	<p>Consider calcium and vitamin D supplementation prior to discharge for patients who are on high dose steroids. Other medications for maintenance of bone health may need to be considered as appropriate.</p> <ul style="list-style-type: none"> Calcium carbonate and colecalciferol (Caltrate® 600mg/400 units) one tablet BD

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Hepatic veno-occlusive disease (VOD):

- Defibrotide may be prescribed for the treatment of VOD in consultation with the haematology consultant
- Dosing of IV defibrotide:
 - The recommended dose is 6.25mg/kg IV every 6 hours (25mg/kg/day)
 - Calculate the total daily dose. Divide by 200 to calculate the total number of vials needed and split the dose such that the minimum amount of wastage can be achieved
 - Defibrotide should be administered for a minimum of 21 days and continued until the signs and symptoms of VOD resolve
 - IV infusion is given over 2 hours (maximum concentration 400mg/100mL NaCl 0.9%)

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) and SJH Stem Cell Transplant Programme PPPGs for full details

DRUG INTERACTIONS:

- Current Summary of Product Characteristics (SmPC) and drug interaction databases should be consulted for information

REFERENCES:

1. Shaw BE, Jimenez-Jimenez AM, Burns LJ, Logan BR, Khimani F, Shaffer BC, Shah NN, Mussetter A, Tang XY, McCarty JM, Alavi A, Farhadfar N, Jamieson K, Hardy NM, Choe H, Ambinder RF, Anasetti C, Perales MA, Spellman SR, Howard A, Komanduri KV, Luznik L, Norkin M, Pidala JA, Ratanatharathorn V, Confer DL, Devine SM, Horowitz MM, Bolaños-Meade J. National Marrow Donor Program-Sponsored Multicenter, Phase II Trial of HLA-Mismatched Unrelated Donor Bone Marrow Transplantation Using Post-Transplant Cyclophosphamide. J Clin Oncol. 2021 Jun 20;39(18):1971-1982. doi: 10.1200/JCO.20.03502. Epub 2021 Apr 27.
2. A Randomized, Multicenter, Phase III Trial of Tacrolimus/Methotrexate versus Post-Transplant Cyclophosphamide/Tacrolimus/Mycophenolate Mofetil in Non-Myeloablative/Reduced Intensity Conditioning Allogeneic Peripheral Blood Stem Cell Transplantation. Javier Bolaños-Meade, MD and Shernan Holtan, MD. Available at: https://cdn.clinicaltrials.gov/large-docs/41/NCT03959241/Prot_SAP_ICF_000.pdf
3. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: <https://pubmed.ncbi.nlm.nih.gov/37269847/>
4. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. Available at: <https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf>
5. Busilvex® 6mg/mL Summary of Product Characteristics. Accessed August 2025. Available from NCCP upon request.
6. Fludarabine 25mg/mL Accord Summary of Product Characteristics. Accessed July 2025. Available at: https://assets.hpra.ie/products/Human/30862/Licence_PA2315-035-001_02062023143321.pdf

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7. cycloPHOSphamide 500mg powder for injection Seacross Summary of Product Characteristics.
 Accessed: 07/08/2025. https://assets.hpra.ie/products/Human/40371/Licence_PA22766-013-002_06122024142806.pdf

Version	Date	Amendment	Approved By
1	05/09/2025		SJH Stem Cell Transplant Group

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

ⁱ This is an unlicensed indication for the use of busulfan and fludarabine in Ireland. Patients should be informed of this and consented to treatment in line with the hospital's policy on the use of unlicensed medication and unlicensed or "off label" indications. Prescribers should be fully aware of their responsibility in communicating any relevant information to the patient and also ensuring that the unlicensed or "off label" indication has been acknowledged by the hospital's Drugs and Therapeutics Committee, or equivalent, in line with hospital policy

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