BCCA Protocol Summary for Treatment of Cutaneous T-cell Lymphoma (Sézary syndrome) with Extracorporeal Photopheresis

Protocol Code *ULYMFECP*

Tumour Group *Lymphoma*

Contact Physician *Dr. Nicholas Voss*

ELIGIBILITY:

- Special: Only patients with advanced, progressive, refractory cutaneous T-cell lymphoma (erythroderma or stages T2/3 with circulating Sézary cells) who have failed at least two prior systemic chemotherapy agents, not including retinoids, and have failed or are unable to tolerate Bexarotene should be considered for ECP. This means that they have either failed to respond to or have relapsed after these treatments.
- Histology: mycosis fungoides or Sézary syndrome
- Adequate immune system with near normal WBC (excluding Sézary cells)
- Normal/near normal CD8 count
- *An "Undesignated Indications Request Form" must be approved.*

EXCLUSIONS:

- Large tumour burden
    - Lymphocytes greater than 25,000
    - Bulky adenopathy greater than or equal to 7 cm
    - Overt visceral organ involvement
    - Multiple tumours
- Large cell transformation
- Significant immunosuppression
- Hypersensitivity to Psoralen
- HIV positive
- Considered on an individual basis: hepatitis B and C
- Insufficient venous access
- Prior prolonged combination chemotherapy or prolonged multiple courses of single agent chemotherapy

TESTS:

- Baseline: CBC and diff, platelets, smear for Sézary cells, CD4 and CD8 counts, LDH, PTT, INR, HBsAg, HBcoreAg
- Before each treatment: CBC and diff, platelets

PREMEDICATIONS:

None

TREATMENT:

Drug	Dose	BCCA Administration Guideline
Extracorporeal Photopheresis (ECP) 8-methoxypsoralen (Uvadex)	0.017 times the final buffy coat volume in millilitres (varies from 3-6 mL/treatment; 6 to 12 mg on two consecutive days every 4 weeks	Infused into the product bag immediately before phototherapy

Reassess all sites of disease after 6 months. Initial treatment is 6 months. Consider a further 6 months of treatment for responders

DOSE MODIFICATIONS:

None

PRECAUTIONS:

1. **Photosensitivity**: Minimise exposure to sunlight and artificial UV light during treatment. It is recommended that patients wear sunscreen greater than or equal to SPF 15 and sunglasses for 24 hours after treatment.
2. **Hepatitis B Reactivation**: All lymphoma patients should be tested for both HBsAg and HBcoreAb. If either test is positive, such patients should be treated with Lamivudine 100 mg/day orally, for the entire duration of chemotherapy and for six months afterwards. Such patients should also be monitored with frequent liver function tests and hepatitis B virus DNA at least every two months. If the hepatitis B virus DNA level rises during this monitoring, management should be reviewed with an appropriate specialist with experience managing hepatitis and consideration given to halting chemotherapy.

Call Dr. Nicholas Voss or alternate at (604) 877-6000 or 1-800-663-3333 with any problems or questions regarding this treatment program.

Date activated: 01 Apr 2006

Date revised: 01 May 2009 (unsafe abbreviations and symbols replaced)

References:

1. Bisaccia E, Gonzalez J, Palangio M, Schwartz J, Klainer AS. Extracorporeal Photochemotherapy alone or with adjuvant therapy in the treatment of cutaneous T-cell lymphoma: a 9-year retrospective study at a single institution. Journal of the American Academy of Dermatology 2000;43(2 Pt 1):263-71. (7).
2. Gottlieb SL, Wolfe JT, Fox FE, DeNardo BJ, Macey WH, Bromley PG, et al. Treatment of cutaneous T-cell lymphoma with extracorporeal photopheresis monotherapy and in combination with recombinant interferon alfa: a 10-year experience at a single institution.[comment]. Journal of the American Academy of Dermatology 1996;35(6):946-57.Gottlieb. (3)
3. Heald P, Rook A, Perez M, Wintroub B, Knobler R, Jegasothy B, et al. Treatment of erythrodermic cutaneous T-cell lymphoma with extracorporeal photochemotherapy.[comment]. Journal of the American Academy of Dermatology 1992;27(3):427-33. (8)
4. Rook AH, Suchin KR, Kao DM, Yoo EK, Macey WH, DeNardo BJ, et al. Photopheresis: clinical applications and mechanism of action. Journal of Investigative Dermatology Symposium Proceedings 1999;4(1):85-90. (6)