

SPLIT			
\$sitecode	User:	System Date:	Mode: Development
Site Name:			

Symptomatic EBV/LPD Evaluation (ELE)

Version: 5.0; 12-05-07

Segment (*PROTSEG*):

Visit Number (*VISNO*):

Date of disease diagnosis:

09/01/2006

Complete when EBV or LPD disease is diagnosed.

1. Signs or symptoms suggestive of EBV disease/LPD: (ELEDIAG) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

Code each:

- a. Fever: (*ELEFEVER*) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
- b. Stridor: (*ELESTRID*) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
- c. Lymphadenopathy: (*ELELYMPH*) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes to lymphadenopathy, code the following:

- | | | | |
|--|---------------------------------|----------------------------------|--|
| 1. Laryngeal, pharyngeal, or tonsils: (EELPHAR) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| 2. Peripheral (axilla, groin, neck): (EELPERI) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| 3. Intra-abdominal: (EELABDM) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| 4. Intrathoracic: (EELTHOR) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| d. GI (diarrhea, abdominal/intestinal mass, GI bleeding, etc.): (ELEGI) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| e. Hepatic (hepatomegaly, jaundice, abnormal LFTs, etc.): (ELEHEPAT) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| f. Increasing spleen size: (ELEINCSP) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| g. Lung: (ELELUNG) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| h. CNS: (ELECNS) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |
| i. Other: (ELEOTHSY) | <input type="checkbox"/> No - 0 | <input type="checkbox"/> Yes - 1 | <input type="checkbox"/> Not evaluated - 2 |

If *Other*, please specify: (ELESYMOT)

2. Diagnosis of EBV disease: (ELEEBVDG) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, code each:

- a. Seroconversion: (ELESERO) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, code:

VCA IgM positive: (*ELEVIPOS*)

☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

IgG positive defined as a minimum four-fold increase in titer: (ELEIGGPS)

☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

- b. Circulating EBV DNA by PCR: (ELECEDBP) ☐ Negative/Undetectable-0 ☐ Positive-1 ☐ Not evaluated-2

If Positive, please enter the viral load, units, and source. If Negative, please enter the lower limit of detection of the PCR assay for the viral load and units, if known.

Viral load: (ELEVLT)

< _____
> (ELEVIRAL) (xxxxxx)

Units: (ELEVUNIT)

copies / 500 ng DNA - 1
genomes / 10⁵ lymphocytes - 2
copies DNA / μ l - 3
cells / 10⁶ PBMC - 4
copies / mcg PBMC DNA - 5
*Additional Options Listed Below

If *Other*, specify: (ELEVUNTO)

Source: (ELEVSRCE)

Whole blood - 1
Plasma - 2
Serum - 3

c. EBV virus demonstrated in tissue (in-situ stain): (ELEPOSTS) ☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2

If Yes, code each:

Tissue biopsied	0- Positive	1- Negative	2- Not biopsied
Lymph node:	(ELETLYMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver:	(EETLIVR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GI tract:	(ELETGTR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lung:	(EETLUNG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	(ELETOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If Other, please specify: (ELETISOT) _____

3. Biopsy for LPD: (ELEBLPD)

☐ No - 0 ☐ Yes - 1

Tissue biopsied	0- Positive	1- Negative	2- Not biopsied
Lymph node or tonsils:	(ELETBLYM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver:	(ELETBLIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GI tract:	(ELETBGIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lung:	(ELETBLUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	(ELETBOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If Other, please specify: (ELEBIOPO) _____

LPD Type

a. B-Cell: (ELEBCCELL)

☐ No - 0 ☐ Yes - 1

If Yes, code the following:

1. Monomorphic: (ELEMOMOM)

☐ No - 0 ☐ Yes - 1

2. Polymorphic: (ELEPOLYM)

☐ No - 0 ☐ Yes - 1

3. Unknown: (ELEUNK)

☐ No - 0 ☐ Yes - 1

b. T-Cell: (ELETCELL)

☐ No - 0 ☐ Yes - 1

4. Immunosuppression prior to diagnosis or signs and symptoms of EBV disease/LPD:

	Code each	Alternate day	Trough level	CsA formulation
Steroids:	(ELEIMSTE) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1	(ELEALTST) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1		
Tacrolimus:	(ELEIMTAC) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1		(ELETTAC) <input type="text"/> (xxxx.xx)	
CsA:	(ELEIMCSA) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1		(ELETCSA) <input type="text"/> (xxxx.xx)	Sandimmune - 0 Neoral - 1 (ELECSAFR) Generic under formulation - 2
Mycophenolate Mofetil:	(ELEIMMYC) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1			
Azathioprine:	(ELEIMAZA) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1			
Sirolimus:	(ELEIMRAP) <input type="checkbox"/>			

	No - 0 <input type="checkbox"/> Yes - 1
Other:	(ELEIMOTH) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1

If *Other*, please specify: (ELEIMOT)

5. Initial treatment of EBV disease/LPD:

Formulation

Steroids:

(ELESTER)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

Tacrolimus:

(ELETACST)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

CsA:

(ELECYCST)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

(ELEFRCSA)

Sandimmune - 0
Neoral - 1
Generic under formulation - 2

Mycophenolate Mofetil:

(ELEMICO)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

Azathioprine:

(ELEAZAT)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

Sirolimus:

(ELERAPA)

Stopped - 1
Decreased dose - 2
Increased dose or initiated - 3
No change - 4
Not giving - 5

Ganciclovir:

(ELEGANCI)

Increased dose or initiated - 3
No change - 4
Not giving - 5

Acyclovir:

(ELEACYCL)

Increased dose or initiated - 3
No change - 4
Not giving - 5

CMV hyper immunoglobulin:

(ELECMVIG)

Increased dose or initiated - 3
No change - 4
Not giving - 5

Immunoglobulin:

(ELEIMGB)

Increased dose or initiated - 3
No change - 4
Not giving - 5

Low dose Cytosan:

(ELELDCYT)

Increased dose or initiated - 3
 No change - 4
 Not giving - 5

Systemic chemotherapy:

(ELECHEMO)

Increased dose or initiated - 3
 No change - 4
 Not giving - 5

Interferon:

(ELEINTER)

Increased dose or initiated - 3
 No change - 4
 Not giving - 5

Anti CD20 mAb (Rituximab):

(ELEACD20)

Increased dose or initiated - 3
 No change - 4
 Not giving - 5

Surgical excision of discrete lesions:

(ELESURGX)

Not done - 0
 Partial excision - 4
 Complete excision - 5

Other:

(ELETROTH)

Stopped - 1
 Decreased dose - 2
 Increased dose or initiated - 3
 No change - 4
 Not giving - 5

If *Other*, please specify: (ELETROT)

6. Did the patient receive monoclonal or polyclonal therapies for induction or rejection? (ELEMPTHE)

☐ No - 0 ☐ Yes - 1
If *Yes*, please specify:

Type of therapy	Received?	Number of courses	Total # of days
ALG/ATG/ALS:	(ELEALG) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1	(ELENALG) (xx)	(ELENDALG) (xx)
OKT3/Monoclonal:	(ELEOKT) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1	(ELENOKT) (xx)	(ELENDOKT) (xx)
IL-2 Mab:	(ELEMAB) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1	(ELENMAB) (xx)	(ELENDMAB) (xx)
Other:	(ELETHOTH) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1	(ELENCOth) (xx)	(ELENDOTH) (xx)

If *Other*, please specify: (ELETHEOT)

7. Comments: (ELECOMM)

Additional Selection Options for ELE

Units:

copies / ml - 6

Other - 9

