

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

Symptomatic EBV/LPD Followup (ELF)

Version: 5.0; 12-20-07

Segment (PROTSEG):**Visit Number (VISNO):****Disease diagnosis date:****09/01/2006****Date of last assessment:**

1. Date of EBV disease/LPD followup evaluation or resolution: (ELFDATE)

2. EBV disease (ELFSEBV)

 (mm/dd/yyyy)

New - 1 ☐

Continuing - 2 ☐

Resolved - 3 ☐

OR

LPD not associated with EBV disease (ELFSLPDN)

New - 1 ☐

Continuing - 2 ☐

Resolved - 3 ☐

OR

LPD associated with EBV disease (ELFSLPDW)

New - 1 ☐

Continuing - 2 ☐

Resolved - 3 ☐

If any of the above are New, complete this form, and enroll the participant into a new EBV/LPD segment

3. Signs or symptoms suggestive of persistent EBV disease/LPD? (ELFSYMPT)

☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
If Yes, code each of the following:

a. Fever: (ELFFEVER)

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

b. Stridor: (ELFSTRID)

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

c. Lymphadenopathy: (ELFLYMPH)

☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
If Yes to lymphadenopathy, code the following:

1. Laryngeal, pharyngeal, or tonsils: (ELFLPHAR)

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

2. Peripheral (axilla, groin, neck): (ELFLPERI)

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

3. Intra-abdominal: (ELFLABDM)

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

4. Intrathoracic: (ELFLTHOR)

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

d. GI (diarrhea, abdominal/intestinal mass, GI bleeding, etc.): (ELFGI)

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

e. Hepatic (hepatomegaly, jaundice, abnormal LFTs, etc.): (ELFHEPAT)

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

f. Increasing spleen size: (ELFINCSP)

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

g. Lung: (ELFLUNG)

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

h. CNS: (ELFCNS)

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

i. Other: (ELFOTHSY)

☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
If Other, please specify: (ELFSYMOT)


4. Followup EBV disease evaluation results: (ELFFER)


☐ No - 0 ☐ Yes - 1 ☐ Not evaluated - 2
If Yes, indicate:

a. Circulating EBV DNA by PCR: (ELFCEDBP)

☐ 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.

Source: (ELFVSRCE)

< 

>  (ELFVIRAL) (xxxxxx)

copies / 500 ng DNA - 1
genomes / 10^5 lymphocytes - 2
copies DNA / μ l - 3
cells / 10^6 PBMC - 4
copies / mcg PBMC DNA - 5
*Additional Options Listed Below

Whole blood - 1
Plasma - 2
Serum - 3

If Yes, code each of the following:

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

Tissue Biopsied	0- Positive	1- Negative	2- Not Biopsied
Lymph node or tonsils:	(ELFTLYMP) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver:	(ELFTLIVR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GI tract:	(ELFTGITR) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lung:	(ELFTLUNG) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	(ELFTOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If *Other*, please specify: (ELFTISOT)

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

If Yes for a new biopsy, indicate tissue biopsied:

Tissue Biopsied	0- Positive	1- Negative	2- Not Biopsied
Lymph node or tonsils:	(ELFTBLYM) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Liver:	(ELFTBLIV) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GI tract:	(ELFTBGIT) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lung:	(ELFTBLUN) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other:	(ELFTBOTH) <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If *Other*, please specify: (ELFBIPO)

If biopsy performed, answer the following:

☐ No - 0 ☐ Yes - 1

If Yes, code the following:

☐ No - 0 ☐ Yes - 1☐ No - 0 ☐ Yes - 1☐ No - 0 ☐ Yes - 1☐ No - 0 ☐ Yes - 1

6. Immunosuppression:

	Currently Using	Maintenance or Reduced	CsA Formulation
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Steroids:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFSTED)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFSTEMR)	
Tacrolimus:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFTACD)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFTACMR)	
CsA:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFCSAD)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFCSAMR)	<input type="checkbox"/> Sandimmune - 0 <input type="checkbox"/> Neoral - 1 <input type="checkbox"/> Generic under formulation - 2 (ELFCSAFR)
Mycophenolate Mofetil:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFMYCD)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFMYCMR)	
Azathioprine:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFAZAD)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFAZAMR)	
Sirolimus:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFRAPD)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFRAPMR)	
Other:	<input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1 (ELFOTH D)	<input type="checkbox"/> Maintenance - 1 <input type="checkbox"/> Reduced - 2 (ELFOTHMR)	

If Other, please specify: (ELFIMOTH)

7. Other treatment of EBV disease/LPD:

	# Days Treated Since Last Assessment	Currently Using
Ganciclovir:	(ELFNDGAN) (xxx)	(ELFGANCI) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Acyclovir:	(ELFNDACY) (xxx)	(ELFACYCL) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
CMV hyperimmuno globulin:	(ELFNDCMV) (xxx)	(ELFCMVHI) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Immunoglobulin:	(ELFNDGLB) (xxx)	(ELFIMMUN) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Interferon:	(ELFNDINT) (xxx)	(ELFINTER) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Low dose Cytosan:	(ELFLDCYD) (xxx)	(ELFLDCYT) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Systemic chemotherapy:	(ELFNDSCH) (xxx)	(ELFCHEMO) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Anti CD20 mAb (Rituximab):	(ELFD CD20) (xxx)	(ELFACD20) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Surgical excision of discrete lesions:		(ELFSURG X) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1
Other:	(ELFNDTRO) (xxx)	(ELFTROTH) <input type="checkbox"/> No - 0 <input type="checkbox"/> Yes - 1

If Other, specify: (ELFTROT1)

8. If immunosuppression was stopped or reduced, did the participant develop rejection? (ELFREJEC)

☐ No - 0 ☐ Yes - 1 ☐ Not applicable - 9

9. Comments: (ELFCOMM)

Additional Selection Options for ELF

Units:

copies / ml - 6

Other - 9

