CVS/caremark

PRIOR AUTHORIZATION CRITERIA

DRUG CLASS	**ALFA INTERFERONS**
BRAND NAME	**INTRON A** **INTRON A W/ DILUENT**
(generic)	**(interferon alfa-2b)**
Status: CVS/caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 555-A***

FDA-APPROVED INDICATIONS[1]

- AIDs-related Kaposi's sarcoma
- Chronic hepatitis B virus infection
- Chronic hepatitis C virus infection
- Condylomata acuminata
- Follicular non-Hodgkin's lymphoma
- Hairy cell leukemia
- Malignant melanoma

Compendia Uses

- Giant cell tumor of the bone[2]
- Chronic myelogenous leukemia (CML)[2-4]
- Renal cell carcinoma (RCC)[2-4]
- Systemic light chain amyloidosis[2]
- Adult T-cell leukemia/lymphoma (ATLL)[2]
- Mycosis Fungoides (MF)/Sezary syndrome (SS)[2-4]
- Desmoid tumors (soft tissue sarcoma)[2]
- Polycythemia vera[3,5]
- Acute hepatitis C virus infection[3,4]

CRITERIA FOR APPROVAL

1	Is Intron-A prescribed for the treatment of any of the following diagnoses: 1) Adult T-cell leukemia/lymphoma, 2) AIDS-related Kaposi sarcoma, 3) Desmoid tumors (soft tissue sarcoma), 4) Follicular non-Hodgkin's lymphoma, 5) Giant cell tumor of the bone, 6) Hairy-cell leukemia, 7) Mycosis fungoides or Sezary syndrome, 8) Polycythemia vera, OR 9) Systemic light chain amyloidosis. 10) Melanoma, 11) Renal cell carcinoma? [If yes, no further questions.]	Yes	No
2	Is Intron-A prescribed for the treatment of any of the following diagnoses: 1) Chronic hepatitis C virus infection, 2) Chronic hepatitis B virus infection, OR 3) Acute hepatitis C virus infection? [If yes, no further questions.]	Yes	No
3	Is Intron-A prescribed for treatment of condylomata acuminate (genital warts) and the patient is not a candidate for one standard treatment option (e.g., podofilox, imiquimod, cryotherapy, podophyllin resin) [If yes, no further questions.]	Yes	No
4	Is Intron-A prescribed for treatment of chronic myelogenous leukemia (CML) and meet either of the following criteria: 1) Patient is unable to tolerate tyrosine kinase inhibitor(s) OR	Yes	No

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2) Patient is post hematopoietic stem cell transplant?

Guidelines for Approval					
Duration of Approval	**12 months**	**Duration of Approval**	**48 weeks**	**Duration of Approval**	**12 months**
Set 1: ATLL, AIDS-related Kaposi sarcoma, desmoid tumors, FL, GCTB, hairy-cell leukemia, MF/SS, polycythemia vera, systemic light chain amyloidosis, melanoma, RCC		**Set 2:** Chronic Hep C, Chronic Hep B, Acute Hep C		**Set 3:** Condylomata acuminata	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	2	1	3	1
					2
Duration of Approval	**12 months**	**Duration of Approval**	**12 months**	**Duration of Approval**	**12 months**

Set 4: CML	
Yes to question(s)	**No to question(s)**
4	1
	2
	3

Internal Use Only – Mapping Instructions		
	Yes	**No**
1.	Approve, 12 months	Go to 2
2.	Approve, 48 weeks	Go to 3
3.	Approve, 12 months	Go to 4
4.	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare-approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Intron A [package insert]. Whitehouse Station, NJ: Schering Corporation; February 2016.
2. The NCCN Drugs & Biologics Compendium™ © 2015 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed April 01, 2016.
3. Micromedex Solutions [database online]. Ann Arbor, MI: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed April 01, 2016.
4. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. April 01, 2016.
5. CVS Clinical Consult. CVS Caremark Clinical Programs Review: Focus on Hematology-Oncology Clinical Programs. September 12, 2012.

DOCUMENT HISTORY

Written: UM Development (LS) 07/1998

Revised: LS 04/1999, 03/2001, 08/2001 JG 02/2002, 11/2002, 01/2004; TM 11/2004, 03/2005, 05/2005; NB 07/2006(3);

	Specialty Clinical Development (MG) 06/2007; 08/2008; GY 11/2009; AC 09/2010, 10/2011 (CMS); KH 12/2011; AC 09/2012 (CMS); HY 01/2013, 09/2013 (CMS), LD 05/2013, ST 03/2014, 09/2014 (CMS); JP 03/2015; ST 08/2015 (CMS); PK 04/2016 (removed “up to” per prior year CMS comment); JP 06/2016 (CMS), PK 07/2017
Reviewed:	CRC 8/1998, 4/1999, 04/2001, 08/2001, 02/2002; 12/2002; 01/2004; CDPR/MM 03/2005, 06/2005, 07/2006; WLF 06/2007, 08/2008; KP 11/2009, 10/2010, 01/2012; DR 05/2012; KP 01/2013, LCB 05/2013; SES 04/2014, 03/2015, DHR 04/2016
External Review:	05/2002; 02/2003; 02/2004; 11/2005; 12/2006, 09/2007, 12/2008, 12/2009, 12/2010, 02/2012, 09/2012, 03/2013, 07/2013, 07/2014, 06/2015, 06/2016