

**EVIDENCE-BASED CRITERIA  
SECTION: LABORATORY**

**ORIGINAL EFFECTIVE DATE:** 02/07/23  
**LAST REVIEW DATE:** 02/07/23  
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## **IMMUNE CELL FUNCTION ASSAY**

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Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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## **IMMUNE CELL FUNCTION ASSAY (cont.)**

### **Description:**

Careful monitoring of lifelong immunosuppression is required to ensure the long-term viability of solid organ allografts without incurring an increased risk of infection. The monitoring of immunosuppression parameters attempts to balance the dual risks of rejection and infection. It is proposed that individual immune profiles, such as an immune cell function assay, will help assess the immune function of the transplant recipient and individualize immunosuppressive therapy.

### **Immunosuppression for Transplant**

In current clinical practice, levels of immunosuppression in individuals being managed after a solid organ transplant or hematopoietic cell transplantation are determined by testing for clinical toxicity (e.g., leukopenia, renal failure) and by therapeutic drug monitoring when available. However, drug levels are not a surrogate for overall drug distribution or efficacy because pharmacokinetics often differ among individuals due to clinical factors such as underlying diagnosis, age, sex, and race; circulating drug levels may not reflect the drug concentration in relevant tissues; and serum level of an individual immunosuppressant drug may not reflect the cumulative effect of other concomitant immunosuppressants. The main value of therapeutic drug monitoring is the avoidance of toxicity. Individual immune profiles, such as an immune cell function assay, could support clinical decision making and help to manage the risk of infection from excessive immunosuppression and the risk of rejection from inadequate immunosuppression.

### **Treatment**

Several commercially available tests of immune cell function have been developed to support clinical decision making.

ImmuKnow measures the concentration of adenosine triphosphate (ATP) in whole blood after a 15- to 18-hour incubation with phytohemagglutinin (a mitogenic stimulant). Cells that respond to stimulation show increased ATP synthesis during incubation. Concurrently, whole blood is incubated in the absence of stimulants for the purpose of assessing basal ATP activity. CD4-positive T lymphocytes are immunoselected from both samples using anti-CD4 monoclonal antibody-coated magnetic particles. After washing the selected CD4-positive cells on a magnet tray, a lysis reagent is added to release intracellular ATP. A luminescence reagent added to the released ATP produces light measured by a luminometer, which is proportional to the concentration of ATP. The characterization of the cellular immune response of a specimen is made by comparing the ATP concentration for that specimen with fixed ATP production ranges.

Pleximmune measures CD154 expression on T-cytotoxic memory cells in individual's peripheral blood lymphocytes. CD154 is a marker of inflammatory response. To characterize the risk of rejection, the individual's inflammatory response to transplant donor cells is expressed as a fraction of the individual's inflammatory response to third-party cells. This fraction or ratio is called the Immunoreactivity Index (IR). If the donor-induced response exceeds the response to third party cells, the individual is at increased risk for rejection. Cells are cultured and then analyzed with fluorochromestained antibodies to identify the cells expressing CD154. For posttransplant blood samples, an IR greater than 1.1 indicates an increased risk of rejection, and an IR less than 1.1 indicates a decreased risk of rejection. For pretransplant samples, the threshold for IR is 1.23.

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## **IMMUNE CELL FUNCTION ASSAY (cont.)**

### **Description:** (cont.)

Immune cell function assay's cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process include: ImmuKnow®, Immune Cell Function Assay, and Pleximmune™.

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### **Criteria:**

- Use of immune cell function assay testing to monitor and predict immune function after solid organ transplantation is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting
- Use of immune cell function assay testing to monitor and predict immune function after hematopoietic cell transplantation is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting
- Use of immune cell function assay testing for all other indications is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  5. Insufficient evidence to support improvement outside the investigational setting

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**NEXT ANNUAL REVIEW DATE: 1ST QTR 2024**

## **IMMUNE CELL FUNCTION ASSAY (cont.)**

### **Resources:**

**Literature reviewed 02/07/23. We do not include marketing materials, poster boards and non-published literature in our review.**

**Resources prior to 02/07/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. Allen UD, Preiksaitis JK, Practice ASTIDCo. Post-transplant lymphoproliferative disorders, Epstein-Barr virus infection, and disease in solid organ transplantation: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. Sep 2019;33(9):e13652. doi:10.1111/ctr.13652
2. Ashokkumar C, Soltys K, Mazariegos G, et al. Predicting Cellular Rejection With a Cell-Based Assay: Preclinical Evaluation in Children. *Transplantation*. Jan 2017;101(1):131-140. doi:10.1097/TP.0000000000001076
3. Ashokkumar C, Talukdar A, Sun Q, et al. Allospecific CD154+ T cells associate with rejection risk after pediatric liver transplantation. *Am J Transplant*. Jan 2009;9(1):179-91. doi:10.1111/j.1600-6143.2008.02459.x
4. Bhorade SM, Janata K, Vigneswaran WT, Alex CG, Garrity ER. Cylex ImmuKnow assay levels are lower in lung transplant recipients with infection. *J Heart Lung Transplant*. Sep 2008;27(9):990-4. doi:10.1016/j.healun.2008.06.005
5. Cabrera R, Ararat M, Soldevila-Pico C, et al. Using an immune functional assay to differentiate acute cellular rejection from recurrent hepatitis C in liver transplant patients. *Liver Transpl*. Feb 2009;15(2):216-22. doi:10.1002/lt.21666
6. Cheng JW, Shi YH, Fan J, et al. An immune function assay predicts post-transplant recurrence in patients with hepatocellular carcinoma. *J Cancer Res Clin Oncol*. Oct 2011;137(10):1445-53. doi:10.1007/s00432-011-1014-0
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8. Food and Drug Administration (FDA). Special 510(k): Device Modification 2010 (K101911). Accessed November 20, 2022. [http://www.accessdata.fda.gov/cdrh\\_docs/reviews/K101911.pdf](http://www.accessdata.fda.gov/cdrh_docs/reviews/K101911.pdf)
9. Food and Drug Administration (FDA). Summary of Safety and Probable Benefit: Pleximmune. 2014. Accessed November 21, 2022. [http://www.accessdata.fda.gov/cdrh\\_docs/pdf13/H130004b.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/H130004b.pdf)

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## IMMUNE CELL FUNCTION ASSAY (cont.)

### Resources: (cont.)

10. Gesundheit B, Budowski E, Israeli M, et al. Assessment of CD4 T-lymphocyte reactivity by the Cylex ImmuKnow assay in patients following allogeneic hematopoietic SCT. *Bone Marrow Transplant.* Mar 2010;45(3):527-33. doi:10.1038/bmt.2009.182
11. Gupta S, Mitchell JD, Markham DW, et al. Utility of the Cylex assay in cardiac transplant recipients. *J Heart Lung Transplant.* Aug 2008;27(8):817-22. doi:10.1016/j.healun.2008.05.014
12. Hashimoto K, Miller C, Hirose K, et al. Measurement of CD4+ T-cell function in predicting allograft rejection and recurrent hepatitis C after liver transplantation. *Clin Transplant.* Sep-Oct 2010;24(5):701-8. doi:10.1111/j.1399-0012.2009.01169.x
13. Husain S, Raza K, Pilewski JM, et al. Experience with immune monitoring in lung transplant recipients: correlation of low immune function with infection. *Transplantation.* Jun 27 2009;87(12):1852-7. doi:10.1097/TP.0b013e3181a75ad2
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17. Kotton CN, Kumar D, Caliendo AM, et al. International consensus guidelines on the management of cytomegalovirus in solid organ transplantation. *Transplantation.* Apr 15 2010;89(7):779-95. doi:10.1097/TP.0b013e3181cee42f
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## IMMUNE CELL FUNCTION ASSAY (cont.)

### Resources: (cont.)

21. Liu W, Wang K, Zhao YH, Song GP, Gao W, Li DH. Clinical relevance of a CD4(+) T cell immune function assay in the diagnosis of infection in pediatric living-donor liver transplantation. *Exp Ther Med*. Nov 2019;18(5):3823-3828. doi:10.3892/etm.2019.8003
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## **IMMUNE CELL FUNCTION ASSAY (cont.)**

### **Resources: (cont.)**

32. Ryan CM, Chaudhuri A, Concepcion W, Grimm PC. Immune cell function assay does not identify biopsy-proven pediatric renal allograft rejection or infection. *Pediatr Transplant*. Aug 2014;18(5):446-52. doi:10.1111/petr.12295
33. Sageshima J, Ciancio G, Chen L, et al. Lack of clinical association and effect of peripheral WBC counts on immune cell function test in kidney transplant recipients with T-cell depleting induction and steroid-sparing maintenance therapy. *Transpl Immunol*. Mar 2014;30(2-3):88-92. doi:10.1016/j.trim.2014.01.003
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35. Shearer GM, Clerici M. In vitro analysis of cell-mediated immunity: clinical relevance. *Clin Chem*. Nov 1994;40(11 Pt 2):2162-5.
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41. Wozniak LJ, Venick RS, Gordon Burroughs S, Ngo KD, Duffy JP, Farmer DG. Utility of an immune cell function assay to differentiate rejection from infectious enteritis in pediatric intestinal transplant recipients. *Clin Transplant*. Feb 2014;28(2):229-35. doi:10.1111/ctr.12303
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<b>ARCHIVE DATE:</b>	

**NEXT ANNUAL REVIEW DATE: 1ST QTR 2024**

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## **IMMUNE CELL FUNCTION ASSAY (cont.)**

### **Resources:** (cont.)

43. Zhou H, Wu Z, Ma L, et al. Assessing immunologic function through CD4 T-lymphocyte adenosine triphosphate levels by ImmuKnow assay in Chinese patients following renal transplantation. *Transplant Proc.* Sep 2011;43(7):2574-8.  
doi:10.1016/j.transproceed.2011.04.012

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### **Coding:**

CPT: 81560, 86352

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### **History:**

#### **Date:**

#### **Activity:**

Medical Policy Panel

02/07/23

Approved guideline

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### **Policy Revisions:**





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LAST CRITERIA REVISION DATE: 02/07/23  
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 1ST QTR 2024

## IMMUNE CELL FUNCTION ASSAY (cont.)

### Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólg dii t'áa hazaadk'ehjí háká a'doowolgo bee haz'á doo baqah ilinígóo. Ata' halne'ígíí kójj' bich'í' hodílnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



**NEXT ANNUAL REVIEW DATE: 1ST QTR 2024**